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HEALTH PROMOTION AND DISEASE PREVENTION

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDRED SECOND CONGRESS

FIRST SESSION

ON

S. 1944

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO STRENGTHEN THE NATION'S HEALTH PROMOTION AND DISEASE PREVENTION ACTIVITIES, AND FOR OTHER PURPOSES.

NOVEMBER 19, 1991

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HEALTH PROMOTION AND DISEASE PREVENTION

TUESDAY, NOVEMBER 19, 1991

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 10:05 a.m., in room SD-430, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the committee) presiding.

Present: Kennedy, Pell, Simon, and Wellstone.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. The committee will come to order.

Our hearing today will discuss two of the most neglected aspects of our health care system—health promotion and disease prevention.

Our Nation spends over $600 billion on health care each year, yet less than 3 percent will be spent on health promotion and disease prevention services.

Over three-quarters of our national health care costs are the result of diseases or injuries that are preventable. Nine preventable chronic diseases are responsible for over 50 percent of all the deaths in the Nation. Chronic diseases such as heart disease and cancer are responsible for over 1.5 million deaths each year.

Cancer continues to be one of the most feared diseases by the American people. One out of four Americans will be diagnosed with cancer. One in nine women will develop breast cancer at some time in their lives. In 1991 it is estimated that 175,000 women will be diagnosed with breast cancer, and 44,500 women will die.

Breast cancer is particularly devastating to a young woman. Although lung cancer has surpassed it as a leading cause of cancer death among women, breast cancer continues to be the leading cause of cancer death among women age 15 to 54, in the prime of their lives and their careers.

Early diagnosis and treatment are the most important factors in controlling this disease. We know that 30 to 40 percent of the deaths could be prevented through regular screening and early detection.

An emphasis on prevention can reduce the toll of many of these serious diseases that affect women.

Cardiovascular disease accounts for 28 percent of all the deaths among women. An estimated 1.3 million osteoporosis-related fractures occur each year, most of them in women. Chlamydia is re-

sponsible for about 500,000 cases of pelvic inflammatory disease, and infertility is a major complication of this disease. Through early detection and treatment, we can prevent 150,000 cases of infertility each year.

Prostate cancer is the most common cancer in American men. It accounted for 103,000 new cases and 28,500 deaths in the United States in 1989. The death rate continues to rise, yet early detection often leads to a cure.

A number of infectious childhood diseases are almost completely preventable through routine immunizations. Before the introduction of the polio vaccine in 1955, more than 20,000 paralytic cases occurred a year. Because of the vaccines, the last outbreak, in 1979, totalled only 10 cases. Yet only 20 to 30 percent of children age 2 and younger have adequate immunizations.

Similarly, measles can be eradicated by immunization. But in 1990 we saw a large and totally unnecessary increase in the number of children with measles with some cases resulting in death or severe disability.

The human costs of these preventable conditions are accompanied by staggering economic costs. Cardiovascular disease costs the Nation $135 billion annually. Cancer costs $70 billion. Pelvic inflammatory disease costs $2.6 billion. Osteoporosis-related fractures cost $10 billion.

The lifetime cost of one child with congenital rubella is $354,000, yet it could have been prevented if the mother had been immunized at a cost of $30.

The treatment of advanced cervical cancer cost $28,000 for the first year, yet screening and early detection would reduce the cost by 50 percent. We pay billions of dollars a year to treat diseases and illnesses that could have been prevented. An ounce of prevention is worth a pound of cure and can save billions of dollars, too.

The effectiveness of preventive health measures has been demonstrated time and again. The control of high blood pressure is one of the most effective means for reducing death rates from heart disease and stroke. The cost-benefit analysis of lead poisoning prevention suggests that for every dollar invested today we will save two in the future.

We can do far more to reduce the physical, emotional and financial burden that result from premature disease, disability and death.

Our hearing this morning will deal with many of these issues, and I look forward to the testimony of our witnesses.

Before we start, I want to especially commend my colleague from Iowa, Senator Harkin, for his work in this area. He has taken a leadership role in the committee and in Congress in promoting increased emphasis on prevention of disease and disability. Much of the Health Promotion and Disease Prevention Act of 1991 is the result of his work.

At this time I would like to submit for the record prepared statements of Senators Harkin, Bingaman, and Hatch.

[The prepared statements referred to follow:]

Prepared Statement of Senator Harkin

Mr. Chairman, I want to thank you for calling today's hearing. As you know, shifting our focus in health care towards prevention has been a top priority of mine.

I believe, Mr. Chairman, that the most fundamental flaw in our health care system today is its preoccupation with patching and mending and its virtual neglect of prevention and health promotion. What we really have in America is not a health care system but a "sick" care system. Over half of the more than $700 billion we will spend this year on health care will go to treat conditions that are preventable. Yet, only a tiny fraction, less than one percent by some estimates, of our health care budget is spent on keeping people healthy and preventing the need for this expensive treatment in the first place. As a result, the quality and length of millions of Americans' lives are needlessly reduced and billions of dollars are needlessly wasted.

Every day we fail to act, more American women die needlessly of breast cancer, more children are damaged for life by preventable conditions like measles and lead poisoning, and more older Americans die prematurely from heart disease and lung cancer.

As it has been in so many other areas, Mr. Chairman, this committee is ahead of the pack on prevention. S. 1944, the package of bills the committee approved unanimously last week, makes great improvements in a wide variety of areas of disease prevention and health promotion. And I am pleased that a number of my ideas and most components of my "Prevention First" initiative are incorporated into that bill.

In addition to serving on this committee, I am chairman of the Appropriations subcommittee which funds our health, education and human services programs. In this capacity, I worked hard with my colleagues to increase support for key prevention programs, including maternal and child health, childhood immunizations, and breast and cervical cancer prevention, in the fiscal year 1992 appropriations bill. We were able to increase funding for these programs by nearly $300 million, or about 30 percent over last year's level. And we paid for most of that increase by rejecting $218 million in increased administrative spending proposed by President Bush. We turned bureaucratic excess into better prenatal care, increased paperwork into more cancer screening for the elderly, and needless staff travel into increased drug abuse prevention for American teenagers. I am very disappointed, therefore, that President Bush is expected today to veto this bill which will do so much to improve the health care available to Americans.

Through these appropriations actions, this hearing and a through passage of S. 1944, we are making a downpayment on what needs to be done to turn our "sick" care system into an American "health" care system of which we can be proud. I look forward to the testimony of our distinguished colleagues and other expert witnesses this morning and to continuing to work with all of you to make prevention a centerpiece of health care reform.

Prepared Statement of Senator Bingaman

Mr. Chairman, I am pleased that you are holding this hearing today, and I want to commend your for demonstrating such a strong commitment to improving the health and well being of all Americans. I am convinced that through your considerable legislative efforts, our nation's quality of life can be significantly improved.

I wish I could have actively participated in today's hearing because I know you will be hearing important testimony from very knowledgeable and dedicated experts in the fields of health promotion and disease prevention. Unfortunately, Mr. Chairman, your appointment of me to the National Commission on Education Standards and Testing prevents me from attending this hearing. look forward to reviewing the hearing record.

Mr. Chairman, over the past several days and weeks, we have heard a lot of talk in the Congress and around the country about the need to find real, lasting, and affordable solutions to our growing crisis in health care—a crisis that threatens to cripple our nation and shatter our ability to compete effectively in the 21st century.

For too long, we have devoted all our resources to mending the cracks in a system. We have now reached a point where we cannot glue the system back together. We must examine the foundation—the underlying myths and beliefs about health care in America. And we must create a national strategy that will help build a healthy, competitive America in the 21st century.

I believe that individual empowerment for good health and disease prevention is a crucial element of that national strategy. Mr. Chairman, when I say "national strategy," I am not talking about a "federal strategy. I am talking about a strategy that includes everyone—all segments of society from the Congress and the administration to state governments, community leaders, and individual family members.

The foundation for this strategy has already been laid by Dr. Louis Sullivan, the Secretary of Health and Human Services. As many of my colleagues know, Dr. Sullivan deserves tremendous credit for his leadership role in coordinating the 3-year development of a comprehensive set of health objectives for the nation. Dr. Sullivan's developmental work culminated in the publication last year of a landmark report entitled *Healthy People 2000.*

Healthy People 2000 sets out three principal goals:

(1) to increase the span of healthy life for Americans;

(2) to reduce health disparities among Americans;

(3) to achieve access to preventive services for all Americans.

To help meet these goals, Dr. Sullivan and his extensive working group developed nearly 300 specific objectives in 22 priority areas. These priority areas include: Physical fitness, nutrition, tobacco use, alcohol and other drug use, family planning, mental health, violence, accidental injury at home and on-the-job, heart disease, cancer, HIV infection, and immunization.

To help ensure that these critical objectives are realized and that the American people understand and appreciate the importance of the objectives, I recently introduced two pieces of legislation based

on the *Healthy People 2000* objectives and my work in New Mexico with an organization I helped establish several years ago, HealthNet New Mexico. I am particularly proud of HealthNet New Mexico, an annual state-wide health promotion campaign that relies heavily on public-private partnerships and the media to get the message of good health, fitness, and better nutrition to people throughout New Mexico.

Through legislation that I plan to introduce next session, I hope to ensure attainment of one of the chief national objectives of the "*Healthy People 2000*" report, that is, to increase to at least 75 percent, the proportion of the Nation's elementary and secondary schools that provide sequential, kindergarten through 12th grade, quality school health education. Passage of this bill would guarantee that all our nation's schools would be empowered to become healthy American schools and that Federal efforts in school health education would be coordinated.

Another of my bills—the Act for a Fit and Healthy America—will help States translate the *Healthy People 2000* objectives into state-wide health promotion programs like "HealthNet New Mexico" and is similar to legislation I introduced in the 99th and 100th Congress on this issue. My other bill will help keep us updated—through a short, easy-to-understand annual report—on our progress, at the national, state, and individual levels, toward achieving the *Healthy People 2000* objectives.

However, if the new statewide health promotion programs that my bill envisions—and, indeed, any program aimed at encouraging progress toward the *Healthy People 2000* objectives are to be successful, they must be supported in every state by strongly-committed individuals. Health care providers, public officials, educators, businessmen and women, and people throughout the community must become personally committed to working in partnership if we are to improve our nation's health care system and ensure its viability in the 21st century. If any of us fail to make that commitment, we all will lose. And if we are serious about a commitment to creating a Healthy America by the year 2000, we have a lot of work to do in the next eight or nine years. I look forward to working with you, Mr. Chairman, toward that goal, and again, I look forward to reviewing today's important testimony. Thank you.

Prepared Statement of Senator Hatch

Mr. Chairman, any sincere attempt to improve the health and well being of Americans must focus on prevention and the promotion of behavior conducive to good health.

We are all familiar with the saying that an ounce of prevention is worth a pound of cure, yet each year the cost to our health care system for preventable illness, injury, and disability runs into the billions. Smoking, the single most preventable cause of death and illness in the United States, costs our health care system over 65 billion dollars annually. The cost of pain and suffering from these avoidable conditions is impossible to measure.

Last week in this committee we reported out S. 1944, the "Health Promotion and Disease Prevention Act of 1991." The Preventive Health and Health Services Block Grant, reauthorized in

this bill, has provided an effective way to pursue national health objectives, while maintaining state flexibility.

The bill assists the States in meeting the Year 2000 National Health Objectives reflected in the *Healthy People 2000* report.

Several new initiatives in S. 1944 target assistance to vulnerable at-risk groups and focus on diseases that continue to cause substantial morbidity and mortality. They emphasize adolescent health, women's health, minority health, and cancer, especially breast and prostate cancer.

Cancer is still responsible for one out of five deaths in this country, with breast cancer being the second leading cause of cancer death among women. An estimated one in ten women will develop breast cancer in the course of her lifetime.

S. 1944 also addresses our infant mortality problem by expanding prenatal and early childhood programs and enhancing our childhood immunization efforts.

While there is still much to be done in this area of health promotion and disease prevention, we know that prevention works. During the 1980's death rates declined for three of the leading causes of death among Americans: Heart disease, stroke, and motor vehicle crashes. Not surprisingly, much of the progress corresponds with reductions in risk factors. The over 40 percent drop in deaths from heart disease since 1970 reflects better high blood pressure detection and control, a decline in cigarette smoking, and a better understanding among Americans of the harmful effects of blood cholesterol and dietary fats.

We must continue our efforts to provide resources, education, training, and guidance. But, we must not forget that while it may be the role of government to provide such assistance, it is ultimately individual behavior that will determine its effectiveness. As Secretary Sullivan has said, "Responsible and enlightened behavior by each and every individual, truly is the key to good health." I look forward to hearing from our panelists today.

The CHAIRMAN. We have some special guests in our audience today—members of the Congressional Wives Organization Initiative Against Breast Cancer. We are delighted to have them here today. We also have members of NABCO, the National Alliance of Breast Cancer Organizations, and we welcome them, as well as members of the National Breast Cancer Resources Committee.

We welcome a colleague and dear friend, the Senator from Alaska, who has played an extremely important role in sounding the alarm about the importance of prevention and routine health examinations.

We are delighted to have him appear this morning. Whether you are a Member of Congress or Senator or an average citizen, it is always difficult to talk about particular health challenges that we face. It is rather intrusive, and I think that by nature and disposition, none of us are terribly eager to share these kinds of personal experiences. But Senator Stevens has been really willing to speak to this issue as he does to so many other matters that he cares deeply about, and because of that it makes an important difference to many of our fellow citizens.

Ted, we're glad to have you here.

STATEMENT OF HON. TED STEVENS, A U.S. SENATOR FROM THE STATE OF ALASKA

Senator STEVENS. Thank you, Senator. I do appreciate S. 1944, your new act dealing with health promotion and disease prevention.

I am here representing Senator Cranston and myself this morning. We are two members of our group here in the Senate who have had cancer, had it diagnosed and dealt with in a different way. Each of us sought our own type of care.

It is estimated that this year 122,000 men will be diagnosed to have prostate cancer, and of those, 32,000 will die. It is the leading, most common cancer among men and is the second leading cause of cancer death for men. But there is great hope now if it is caught early, and that's the reason Senator Cranston and I are speaking out.

If it is detected early, it is curable, and I am here to represent that. Thankfully, I received word just a week ago last Friday of the total removal of the cancer from my system due to the operation that I had.

I think the real problem is that less than 30 percent of the cancers in American men are detected early enough to be in the curable area. Often, men have no visible or painful symptoms. Prostate cancer will strike one in 11 men. There is a 50 percent higher instance in black men in America.

And Senator, there is an interesting environmental component to this cancer. Men in Asia have almost no incidence of prostate cancer, but when they come to our country they end up with the same rates as the general male population. Similarly, black men in Africa have a greatly reduced incidence of prostate cancer, yet black men in America have a rate 50 percent higher than other men in America.

I do think that it is a cancer that deserves increasing attention. The National Cancer Institute is increasing its attention, but the total amount spent on cancers for the male system are about $16–$17 million per year in the total research area.

We think much more needs to be done because of this environmental aspect of the cancer that strikes so many American men.

I do, as I indicated, thank you for your attention to the matter, and I thank you for the invitation to come here—I believe it was Senator Cranston who suggested it. But I want you to know that, as you say, one of the difficult problems is that I've met so many men who have had prostate cancer who just are unwilling to talk about it; they are unwilling to explain to other men the fact that early detection through just a routine physical will save a great deal of time and effort and be a great contribution to our society.

So I do appreciate the provisions in your bill in particular that deal with screening. I think prostate cancer ought to be involved in the screening systems that we set up for those who cannot afford the health insurance or the annual physicals that so many of us are able to get.

I appreciate the opportunity to be with you.

[The prepared statement of Senator Cranston (with attachments) follows:]

Prepared Statement of Senator Cranston

U.S. Senate,
Washington, DC, February 22, 1991.

Dear Male Colleague: In the course of coping with my prostate cancer, I've learned a great deal that has been—to me—startling. I might well have avoided much that I've gone through in the past few months had I been better informed. I am writing to each of you because what I now know might be of help to you.

I have learned that it is probable that each of us if we live long enough will develop prostate cancer. I am shocked that the two most recent deaths of members of the Senate and House, Sparky Matsunaga and Sylvio Conte, were due to prostate cancer.

Fortunately, prostate cancer unlike many other malignancies is usually slow to grow and spread. Unfortunately, a good deal less is known about dealing with prostate cancer than with other cancers because its incidence is relatively rare until men reach their fifties. It's only in recent decades that so many males have begun to live into their sixties, seventies and beyond.

Statistics are sparse, but one reputable study indicates that at least 10 percent of males will have clinically detectable prostate cancer—which may or may not lend to serious health problems—in their fifties. This study indicates that the percentage will double with each passing decade. So 20 percent will have it in their sixties, 40 percent in their seventies, and over 10 percent in their eighties.

If a malignant prostate tumor starts to grow, the odds are that if it is detected early enough it will not require radical treatment. That mine was not detected as early as it might have been was fundamentally my own fault. In 1989, I neglected to get my customary annual physical examination from the Senate physician because I was too busy.

I remembered to go in for a routine physical last fall. It was then that Dr. Robert Krasner, the Senate Pysician, discovered signs of cancer—subtle signs that oncology specialists subsequently told me were not that easy to detect and that many physicians might have missed. The malignancy's actual presence was confirmed by a biopsy at Walter Reed Hospital under the direction of Dr. David McLeod.

I remarked to Dr. Krasner in the course of all this that I wished his office had reminded me to come in for my annual examination after I had failed to show up for it the previous year. I was startled when he responded that for a good number of years it has been the practice of the Senate Physician not to initiate any contacts with members for any reason whatsoever unless specifically instructed to do so by a Senator. In fact, several Senate offices have told the Capitol Physician's office, "Never contact us. We'll contact you.

The record of the Capitol Physician's office in maintaining confidentiality about members' health, so far as I know, has been unblemished at least in recent years. But apparently some members—or their staffs—are more concerned about the potential political consequences of any leak about the member's medical needs than they are about his actual physical well-being. The result is that the health of all members who rely upon the services of the Capitol Physician are potentially being deprived of the full extent of those services.

My message on this point is a simple one: I urge you to take steps to insure that the Capitol Physician, if you are depending upon his care in any regular sense, feels free to communicate with you whenever he deems it appropriate. I want to stress that it is at my initiative, not Dr. Krasner's, that I offer this unsolicited advice.

Dr. Krasner, or your personal physician, can advise you of certain physical signs that can warn you that you may be developing prostate cancer. I had one of those mild signs, but didn't know what it signified, and ignored it. Physicians also can advise you of certain tests beyond the standard digital exploration that can enhance the early detection of a prostate malignancy.

Once I realized what I faced, I immediately consulted a number of oncologists who are generally recognized as the top practitioners of various forms of treatment such as radiation, radical surgery, or various sorts of radioactive implanting.

I proceeded to receive the best possible treatment for my particular condition under the care of the preeminent physician in his field, Dr. Malcolm A. Bagshaw, Chair of Stanford University Medical Center's Department of Radiation Oncology. I received a course of external beam radiation followed by surgery involving brief internal implantation of radioactive needles and the application of heat to the prostate. The side effects have been minimal considering the extent of the treatment.

Should you ever wish me to do so, I'd be glad to save you some time and trouble by sharing with you what I learned about various alternative treatments and the leading oncologists in this field.

I hope the need will never arise, but if it does, I'd be glad, of course, to expand upon any aspect that I've touched upon or left unsaid in this letter.

Sincerely,

ALAN CRANSTON

U.S. SENATE, COMMITTEE ON APPROPRIATIONS,
Washington, DC, September 9, 1991.

U.S. Senate
Washington, DC.

PERSONAL AND CONFIDENTIAL

DEAR : In February, Alan Cranston wrote to urge you to take stops to ensure that you take advantage of the services of the Capitol physician. Doctor Krasner and his staff are available to you—but you must initiate the schedule for an annual medical examination. I know many of you seek medical care elsewhere, but at least 25 percent of us have not had an annual exam.

I spent a large portion of the August recess preparing for and success fully recovering from a prostatectomy—the surgical removal of a cancerous prostate. Changes in my prostate were first noted by Dr. Krasner in a medical examination in his Capitol office. My surgeon was Dr. David McLeod at Walter Reed—in whom I have absolute confidence.

What concerns me, as it did Alan Cranston, is that as we live longer, American males have increased levels of prostate cancer. Alan gave you these statistics, too, but let me repeat them—10 percent of American males have prostate cancer in our fifties. That doubles—or more—every decade. By our eighties, 70 percent of American males will have detectable prostate cancer, and the risk is higher in Black American males.

Enclosed is an article by Ruben F. Gittes, M.D. of Scripps Clinic, reprinted in the New England Journal of Medicine in January 1991. If Sparky Matsunaga or Silvio Conte had read it—and had their annual physical and follow up diagnostic tests, before complications set in, they would probably be with us today.

Alan and I are going to work together to develop some suggestions for steps to increase prostate cancer detection and focus research on urology problems.

But, only you can find out if you have a problem! Obviously, not all male medical problems relate to the prostate—it is just one of the checks in a routine medical exam.

Please, make sure you have a thorough medical examination, at least annually. And, if you ever feel you have a medical problem you don't have the answer to—call Dr. Krasner's office!

Cordially,

TED STEVENS

P.S. If you didn't read Alan Cranston's letter—please, get it out and read it now. I have not repeated all of his message to you.

[Additional copy submitted by Senator Stevens follows:]

United States of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 102d CONGRESS, FIRST SESSION

Vol. 137 WASHINGTON, TUESDAY, SEPTEMBER 10, 1991 No 123

Senate

PROSTATE CANCER

Mr. STEVENS. Mr. President, the majority leader took the time to welcome back our good friend, DAVID PRYOR, and I do also. I am happy to be here to do that, because during the past recess I have a radical prostatectomy, which is the surgical removal of a cancerous prostate. I have taken the occasion to write to every Member of the Senate, as did Senator CRANSTON after his diagnosis, and I want to take this occasion to urge Members of the Senate to read the letter from Senator CRANSTON and my letter.

During my personal investigation of this disease, I have been struck by the statistics that most American men have no knowledge of it. It is the second leading cause of death from cancer, tied with colorectal cancer and exceeded only by lung cancer for American men As a matter of fact, black men in America have twice the rate of all other males in our country. Prostate cancer now is the most common malignant cancer in America, excluding skin cancer. Because our national research expenditures are limited, many American males have died without even knowing they had prostate cancer, or the ability to find out about this disease.

The great tragedy is that American men just do not have annual physicals. That annual physical meant much for me, as the Capitol physician found the signs of some change in my prostate, and the diagnosis, through a series of followups, showed that it was cancer. I did, as I said have it removed.

But I think the message really ought to be today that every American male should have a physical exam once a year after he is 40. Ten percent of American males in their fifties have prostate cancer, but by the time we are in our eighties, 70 percent of American males will have this disease. Really, it is the prospect of early diagnosis that gives hope for total recovery, which is my hope today, and I hope that Senator CRANSTON has the same results.

I once again, Mr. President, urge Members to read Senator CRANSTON'S letter, to read my letter, and I hope that the Senate will pay attention when the various bills come before us as we try to raise the subject of how to increase the research into this disease.

It is interesting, Mr. President, Asiatics, in their home countries, have almost no prostate cancer. When they come to our country, they have the same amount as American males. There is every indication that this is one of the cancers that could be caused by strictly environmental conditions. It is something on which we must follow up. It is something to which we must dedicate more of our attention, and I hope to ask the Senate to do that.

Mr. President, I ask unanimous consent that in the RECORD there be printed, following my remarks, an article that appeared in the New England Journal of Medicine by Dr. Ruben F. Gittes, entitled "Carcinoma of the Prostate."

The PRESIDING OFFICER. Without objection, it is so ordered.

(See exhibit 1.)

Mr. STEVENS. This is something that I have sent to every Member of the Senate, and I think it is too bad that every American male cannot read it.

EXHIBIT 1

[From the New England Journal of Medicine, Jan. 24, 1991]

CARCINOMA OF THE PROSTATE

(By Ruben F. Gittes, M.D.)

In the 12 years since the topic was last reviewed in the Journal,[1] prostatic cancer has become the most common newly diagnosed cancer in men. It is the cause of death in more than 28,000 men per year, accounting for 11 percent of cancer deaths, third in men after lung and colon cancer.[2]

Important questions remain about the cause and prevention of prostatic cancer, but new advances permit earlier diagnosis and more accurate staging. Curative therapy is possible for localized disease with much less morbidity than previously. In advanced disease, androgen-deprivation therapy remains the mainstay of treatment.

BIOLOGY AND EPIDEMIOLOGY

Cause and experimental models

As a secondary sex gland affected by hormonal stimulation and an exocrine gland accessible to retrograde infection, the prostate might well be transformed by carcinogenic influences. However, adenocarcinoma has only rarely been induced experimentally in any animal model with the use of carcinogens or injected hormones.[4] The few animal models we have are serially passaged tumor lines derived from spontaneous tumors detected serendipitously in old rats or from human tumor lines that can grow in nude mice. The well-studied Dunning tumor has been passaged in rats for nearly 30 years and is available in androgen-sensitive and androgen-resistant sublines.[4]

Basic investigation of clinical and experimentally induced prostate tumors has raised the possibility of involvement of the *ras* oncogenes.[5] A new tumor line for basic studies has resulted from infection of fetal cloacal tissues with the *ras* and *myc* oncogenes with use of a viral vector in mice.[6]

Prevalence

Epidemiologic studies have found no consistent correlation of prostatic cancer with diet, venereal disease, sexual habits, smoking, or occupational exposure.[7] However, higher serum testosterone levels have been proposed as a major determinant of the risk of prostatic cancer,[8] as is described below.

An astonishingly high prevalence of what pathologists have interpreted as microscopic foci of well-differentiated adenocarcinoma has been found at autopsy in serial sections of prostate glands considered to be normal from men over the age of 50. Every decade of aging nearly doubles the incidence of such tumors—from 10 percent in men in their 50s to 70 percent in men in their 80s.[9, 10] Since we now estimate that there is only a 6 to 8 percent chance that a man will have a clinically detected prostatic cancer in his lifetime,[2] we can estimate that at least 9 of 10 such cancers remain undetected and clinically unimportant for decades. Such a prevalence of "latent" or "incidental" tumors appears to be unique to the prostate gland.

There are wide geographic and racial differences in the incidence of clinically diagnosed prostatic cancer, ranging from 0.8 case per 100,000 population in Shanghai, China, to 100.3 per 100,000 among blacks in Alameda County, California.[9] Prostatic cancer is more common among blacks and much less common among Asians than among whites. The mortality among men with prostatic cancer, also much higher among blacks,[11] has been ascribed in part to late diagnosis.[12]

Several studies have indicated that the incidence of latent carcinoma at autopsy is similar in different ethnic groups.[13, 14] Since this would seem to eliminate a genetic basis for the appearance of latent prostatic carcinoma, what accounts for the disparate growth of these tiny tumors to clinically important size in different countries and races? An attractive but conjectural hypothesis[8] is that it is the serum testosterone level. Since prostatic cancers are responsive to testosterone, since black men have serum testosterone levels 15 percent higher than white men,[15] and since a vegetarian diet alone may lower serum testosterone levels,[16] the combination of race and diet can predict some if not all of the epidemiologic spectrum of prostatic cancer. Further studies are needed to test this hypothesis.

Familial clustering of clinical cases has been observed, but no chromosomal markers or deletions have been reported. It is estimated that men who have both an affected first-degree relative (a brother or father) and an affected second-degree relative (an uncle or grandfather) have an eightfold increase in risk.[17]

Patterns of growth and spread

Tumors that grow so slowly as to be clinically inconsequential make up the bulk of the incidental tumors.[2, 18] Tumors that do attain clinical importance arise principally in the peripheral zone of the prostate gland, which is usually palpable by rectal examination, and in the transition zone, usually removed during transurethral resection of the prostate.[19, 20] They grow peripherally through the capsule of the prostate,[21, 22] favoring the passage through the perineural spaces that perforate the capsule only at the upper outer corner and at the apex.[23] They frequently invade the seminal vesicles and the neck of the bladder. They rarely cross the fascial space into the rectal wall. Their metastatic spread is both lymphatic and hematogenous. Lymphatic spread is usually orderly and affects the obturator and iliac nodes first.[24] Hematogenous spread occurs overwhelmingly to the bones and less so to the lungs and liver.[25] Spinal involvement frequently extends into the epidural space and is a cause of extrinsic compression of the spinal cord and weakness in [illegible] progressing to paraplegia.

DIAGNOSIS

Detection of prostatic cancer

In asymptomatic patients, a yearly rectal examination after the age of 40 remains the most reasonable screening technique for prostatic cancer. It is estimated that 12,000 prostatic cancers are detected at a curable stage every year in this way.[2,26] The use of other diagnostic tests for mass screening remains controversial and is being evaluated as described below. For symptomatic patients, with presumptive benign prostatic hypertrophy or prostatitis that may be masking a cancer, the past decade has witnessed the introduction of two additional and potentially powerful diagnostic aids—transrectal ultrasonography and determinations of serum levels of prostate-specific antigen.

Transrectal ultrasonography in early detection and biopsy

Transrectal ultrasonography, a continuously improving technique of imaging, has a proved ability to detect hypoechoic lesions (which are consistent with the presence of prostatic cancer) as small as 5 mm in diameter. It is said to detect clinically important lesions that are out of the range of the examining finger, while avoiding the microscopic and still inconsequential lesions of incidental tumors.[27, 28] Transrectal scanning is an unnecessary procedure. The instruments now available are relatively inexpensive and are becoming commonplace in the offices of urologists and in radiology departments. All have probes that guide a biopsy needle and document the exact location of the tissue extracted.

A recently introduced biopsy technique that is generally replacing the use of both conventional large-bore needles for core biopsies[29] and fine-needle-aspiration smears[30] is the use of an intermediate-caliber needle for core biopsies obtained with a spring-loaded biopsy "gun."[31, 32] The thinner needle (18 gauge instead of 14 gauge) more readily allows transrectal or transperineal biopsy with less bleeding than previously. No anesthesia is used, and the performance of multiple biopsies has become quite acceptable. The biopsy gun is used to guide the finger in the case of palpable lesions or through a biopsy channel built into the transrectal-ultrasonography probes now manufactured. Systematic multiple biopsies in a gridlike distribution are increasingly performed to sample suspected prostate tumors even in the absence of lesions obvious on ultrasonography.[33] Hodge et al. have claimed that up to 80 percent of biopsies in patients with suspicious findings on digital rectal examination are now positive, including those in 53 percent in patients with previously negative digitally guided biopsies.[34]

Ultrasound scanning can fail to detect up to 30 percent of the prostatic lesions that are easily palpable on rectal examination, because they are isoechoic instead of hypoechoic. Conversely, the ultrasonic hypoechoic appearance of small tumors, ascribed to their higher cellular density, overlaps considerably with that of nonmalignant tissue affected by inflammation—only 20 percent of hypoechoic areas are cancerous.[35]

Ultrasonography in screening for prostatic cancer

There has been an ongoing controversy about whether screening for prostatic cancer by ultrasound examination has a role at all. Its enthusiasts[36-38] emphasize the limitations for the rectal examination and the opportunity that ultrasound scanning presents for documentation of the ultrasonic consistency of the entire gland. They stress that serial examinations can be reliably compared, defects measured in millimeter, and, of course, ultrasound-guided needle biopsy carried out with very little morbidity. Others are more skeptical[39-42] about the use of ultrasonography for screening. Some point out that there is no proof that the detection or biopsy of these early lesions changes the clinical outlook for the patients.[43] Unfortunately, screening transrectal ultrasonography has been marketed directly to the public in many cities as a life-saving procedure.

Prostate-specific antigen

In the past decade, the search for organ-specific substances in the prostate led to the discovery of prostate-specific antigen.[44] This is a glycoprotein produced uniquely in the cytoplasm of both benign and malignant prostate cells and found in no other normal tissues or tumors.[44] Its unique organ specificity and the wide availability of immunoassays in kit form[45, 46] quickly established prostate-specific antigen as the most sensitive marker of prostatic cancer,[47-49] effectively replacing the venerable test for prostatic acid phosphatase in almost all situations.

A definite elevation in the level of prostate-specific antigen is possible with nonmalignant prostatic disease. Enlarged glands with benign prostatic hypertrophy account for most borderline elevations of the antigen found in clinical practice,[50-54] but an antigen level over 10 ng per milliliter is most unlikely to be due to benign prostatic hypertrophy alone, and urologic evaluation is indicated. Thus, Hudson et al.[51] found that only 2 percent of patients with benign prostatic hypertrophy had antigen levels over 10 ng per milliliter, whereas 44 percent of patients with prostatic cancer, including 36 percent (37 of 103) of those with clinical Stage A or B disease (Fig. 1), had levels over 10 ng per milliliter.

[Figure not reproducible in the Record]

(Figure 1. Preoperative Values for Prostate-Specific Antigen in Patients with Benign Prostatic Hyperplasia (BPH), Clinically Localized Prostatic Cancer, or Metastatic Prostatic Cancer. Solid line denotes the upper limit of the level of prostate-specific antigen in normal men; dashed line denotes the upper limit of patients with BPH. Reproduced from Hudson et al.[51] with the permission of the publisher.)

Injury to normal prostate tissue can raise the level of prostate-specific antigen for several days. Although routine rectal examination has been said to produce a brief false positive elevation of the antigen,[47] Brawer et al. were unable to confirm this finding in a formal study.[55] The half-life of prostate-specific antigen, after the release of a bolus into the blood, has been calculated to be about 2.2 days in one assay[47] and 3.2 days in another.[56] After major trauma, such as a transurethral resection or a needle biopsy of the prostate, it is known that the level of prostate-specific antigen can rise 50-fold and remain elevated for two weeks.[57] Prostatitis can elevate the level of antigen over the short term,[53] as can a prostatic infarct. These, of course, are all transient elevations that, although they may reach the range found in prostatic cancer, should decline on subsequent determinations.

Gram for gram, the average prostatic cancer produces at least 10 times the amount of prostate-specific antigen that is produced by normal prostatic tissue.[48,58] Some small tumors seem to have even more activity, with small nodules producing antigen at levels in the range of 15 to 30 ng per milliliter. Some patients with metastatic disease present with serum levels of several thousand nanograms per milliliter.

The role of prostate-specific antigen in screening for prostatic cancer was prejudiced from the start by the fact that benign prostatic hypertrophy, which is very common, is often associated with a slight elevation in the antigen level.[52,54,59] It is noteworthy that up to 30 percent of localized prostatic cancers have normal antigen values.[60,61] therefore, it is agreed that the measurement of prostate-specific antigen should not displace rectal examination in the early detection of prostatic cancer, but rather complement it.

Cooner et al.[62] and others[63-65] have stressed the complementary use of ultrasound examination and prostate-specific-antigen testing in the evaluation of palpable prostatic cancer. For example, Cooner's group found that of 479 men 60 to 69 years of age with normal results on rectal examination who were studied by the two methods, the combination of transrectal ultrasonogram and an elevated level of prostate-specific antigen (over 4.0 ng per milliliter) identified 17 of 48 biopsy specimens (35 percent) positive for cancer. In a more recent study by Lee et al.[66] of symptomatic patients with normal results on rectal examination, the presence of an elevated antigen level made an abnormal ultrasonogram a positive predictor of cancer in 82 percent of cases, and the presence of both abnormal results on rectal examination and an elevated level of prostate-specific antigen raised the positive predictive value of ultrasonography to 71 percent.[67]

Magnetic resonance imaging in early detection

Newly developed small probes for transrectal magnetic resonance imaging[68] have shown a startling degree of resolution and sensitivity for prostatic cancer as compared with benign prostatic hypertrophy. This technique may prevent unnecessary biopsies and will undoubtedly be applied increasingly to the early diagnosis of prostatic cancer.

Histologic grading of prostatic carcinomas

As with other types of adenocarcinoma, prostatic tumors were for many years graded according to the degree of differentiation.[85] Although individual cells can be graded according to their nucleolar or nuclear roundness,[86,87] as must be done with fine-needle-aspiration-biopsy specimens,[88] the tumor patterns revealed under low-power microscopical examination are particularly distinctive and useful. These patterns range from well-differentiated small glands with "back-to-back" crowding to poorly differentiated sheets or cords of malignant cells.[89, 90]

In the past decade several efforts have been made to adopt a uniform grading system that would correlate with the clinical course of the patients.[91-95] The system of Gleason[93] (Fig. 2) has been incorporated rapidly into clinical practice and appears to correlate well with other known prognostic indicators, especially tumor size,[96] metastases to pelvic lymph nodes,[95, 97-101] and even the level of prostate-specific antigen.[102]

[Figure not reproducible in the Record]

(Figure 2. Simplified Drawing of the Gleason Grading System for Prostatic Adenocarcinoma. Five distinct glandular patterns are identified and shown in order of increasing lack of differentiation. More than one pattern may be present in a surgical specimen; the pathologist identifies the two predominant ones and adds them to yield a final Gleason grade (e.g., 3+4=grade 7). Reproduced with the permission of the publisher.[93])

Biopsy specimens of metastatic tumors of uncertain origin in men are readily identified as prostatic by the routine use of immunohistochemical testing for prostate-specific antigen and prostatic acid phosphatase. Prostate-specific antigen is present in 97 percent of such tumors, even very undifferentiated ones, and the test for prostatic acid phosphatase usually identifies the remainder.[69]

STAGING OF PROSTATIC CANCER

The staging of prostatic cancer is of central importance to any discussion of therapy and clinical results. The commonly used staging systems are shown in Figure 3. Staging has become more elaborate, with the possibility of increased definition of lesions by imaging and the use of tumor markers.

[Figure not reproducible in the Record]

(Figure 3. Staging of Prostate Cancer. The tumor, node, and metastasis (TNM) staging for local tumors is indicated by Roman numerals I through IV. The more elaborate Hopkins system is subdivided to make clinically important distinctions, as follows: Stage A—microscopic, not clinically palpable tumor (A$_1$, with focus in less than 5 percent of tissue examined, low grade; A$_2$, with multiple areas [more than 5 percent] or Gleason grade higher than 4); Stage B—palpable, macroscopic tumor (B$_1$, <1.5 cm in diameter, only in one lobe; B$_2$, >1.5 cm in diameter, or several nodules in both lobes); Stage C—tumor with extracapsular extension, but still clinically localized (C$_1$, palpably extending into seminal vesicle but not fixed to pelvic wall; C$_2$, fixed to pelvic wall); and Stage D—demonstrated metastatic tumor (D$_1$, metastases limited to three pelvic nodes or fewer; D$_2$, more extensive nodal or extrapelvic metastases [e.g., to bone]).)

Measurement of the prostatic-tumor markers, prostate-specific antigen and prostatic acid phosphatase, and total-body bone scanning constitute the usual initial staging evaluation of a patient with proved prostatic cancer. A positive bone scan, usually correlated with the level of prostate-specific antigen, identifies the patient's disease as Stage D$_2$, and makes elaborate local staging unnecessary. If the bone scan is negative, CT or MRI is performed as well to evaluate the pelvic lymph nodes.[69] The extent of local disease may be defined better by ultrasound scanning as an adjunct to the rectal examination.[84]

The role of surgical pelvic lymphadenectomy in staging and in planning for the patient's therapy has become established.[83] This procedure is preliminary to radical prostatectomy (described below); if the frozen sections are positive, no surgical attempt at a cure is made. The usefulness of this procedure has been reinforced by the abandonment of lymphangiography and the poor sensitivity of CT and MRI.[83, 84]

Early hopes that lymphadenectomy of microscopic metastases might be therapeutic have been dispelled, because longer periods of follow-up have shown the inevitable appearance of a distant recurrence in patients with even minimal involvement of lymph nodes.[83]

TREATMENT OF LOCALIZED (STAGES A AND B) PROSTATIC CANCER—RADIATION VERSUS SURGERY

Patients with Stage A prostatic cancer are usually assigned to watchful waiting unless they are relatively young.[83] Radical prostatectomy and radiation therapy both offer curative treatment in patients with early disease that is limited to the prostate (Stages A$_2$, B$_1$, and B$_2$). Neither method has proved statistical superiority in its effectiveness.[83] A prospective randomized study by the Veterans Affairs Oncology Group in which patients were assigned to either radiation therapy or surgery after a negative node dissection indicated an advantage to surgery, as shown by the percentage of patients free of recurrence after five years.[83] However, Bagshaw et al. have retrospectively analyzed the results of radiation therapy at Stanford University and have suggested that they are comparable to the surgical results studied prospectively by the Veterans Affairs group,[76] noting that 90 percent of the patients in a subgroup with negative results on lymphadenectomy remained free of disease after five years. Retrospective reviews of surgical results at several centers suggest a favorable outcome: the 15-year disease-specific survival rate was 93 percent at the Mayo Clinic,[74] 89 percent at the Mason Clinic,[75] and 86 percent at Johns Hopkins Hospital.[73] In these series, disease-specific survival reached a plateau after 10 years.

Nerve-sparing radical prostatectomy

Radical prostatectomy, available for many years, calls for removal of the entire prostate, including the capsule, a layer of surrounding connective tissue, and the attached seminal vesicles. At one time this operation caused permanent impotence in almost all patients. In a landmark contribution, Walsh and Donker[74] determined the anatomical location of previously overlooked nerve bundles that are required for normal erection of the penis. New techniques of radiation prostatectomy can now spare these nerves,[74] and within a year potency returns in 60 to 80 percent of patients so treated. Younger patients with more limited disease have the best rate of recovery.[71, 72]

Another advance has been the notable reduction in blood loss from radical prostatectomy, because of more accurate dissection of the venous channels overlying the proximal urethra and the prostatic apex.[77] It is now customary to have patients donate two units of blood, and with the new procedure they rarely require more than that.[72]

Although almost all centers accept the concept that radical prostatectomy should be aborted if positive pelvic nodes are found,[74] the Mayo Clinic group has proceeded with both prostatectomy and orchiectomy in such cases.[73] Their excellent results are controversial, representing a combination of early adjuvant hormonal therapy and a gland removal of the local tumor.

Concern has recently arisen that the nerve-sparing procedure may impair the overall effectiveness of the surgery.[83, 91] Longer periods of follow-up will be necessary to rule out the risk of increased local recurrence.

Complications of Radical Prostatectomy

Permanent incontinence is now rare, occurring in less than 2 percent of patients.[74, 75] The node dissection and the rest of the pelvic surgery predispose patients to thrombophlebitis and lymphocele.[83] The frequency of lymphocele is increased by prophylaxis with heparin.[83, 84] When, despite a nerve-sparing prostatectomy, impotence does occur and is of concern to the patient, oral administration of papaverine or alprostadil can be used to promote penile erection and are usually successful.[83]

Drop in Level of Prostate-Specific Antigen

With a half-life of two to three days, prostate-specific antigen becomes undetectable soon after curative radical prostatectomy.[91] The methods and techniques used are so accurate and the specificity of origin of any detectable antigen so obvious that the finding of a measurable level after radical prostatectomy leaves no doubt that there are residual prostatic cancer cells.[47, 50, 91, 99]

Radiation therapy

Interstitial radiation using seeds of iodine-125 or gold-198 (brachy-therapy) was in vogue for several years. The early procedure required open surgical exploration, with lymph-node sampling and the placement of needles into the substance of the prostate to deposit the radioactive seeds. Superior results were claimed in terms of preserving potency and avoiding incontinence.[87, 88] Unfortunately, in the past 10 years longer follow-up periods have shown relatively poor local control of the disease by this method.[89, 90] Some centers have continued to administer interstitial radiation, however, using transperineal percutaneous needles guided by ultrasonography.[88, 89]

External-beam radiotherapy from high-energy linear accelerators has been an established and well-tested curative treatment for localized prostatic cancer for more than two decades.[86, 89] Newer energy sources, such as proton beams[87] and neutron beams,[88] have been used to reduce the scatter of the radiation effect further, but they remain experimental and relatively inaccessible.

The role of radiation therapy in treating the pelvic lymph nodes is still controversial.[83, 106] Surgical lymphadenectomy is not usually used for staging before radiation therapy, because of the increased morbidity of the combined methods. On the hypothesis that the progression of microscopic tumors in pelvic lymph nodes might be arrested by suboptimal doses of radiation therapy, most therapeutic programs do administer a wide-field treatment of up to 50 Gy that includes the pelvic lymph nodes and then "cone down" for additional therapy to the more tolerant region of the prostate and the immediate tissues, for a total dose of 70 Gy.[99, 101]

Complications

Potency is preserved in over half the patients who undergo radiation. Thus, Bagshaw et al. reviewed the results in 532 patients and found that 84 percent were potent after 18 months and 60 percent remained so after 7 years.[76] The deleterious effect of the radiation appears to involve nerve conduction less than the patency of the vessels to the corpora cavernosa.[103]

The incidence of rectal-wall damage, formerly an important complication, has been greatly reduced by the use of photons with increased energy and by better targeting of the beams. Temporary tenesmus, diarrhea, and mucosal bleeding are usually the worst problems. Rarely, rectal-wall fibrosis and problems with the function of the rectal ampulla are encountered.[86]

Level of Prostate-Specific Antigen

The course of serum levels of prostate-specific antigen after definitive radiation for presumably localized prostatic cancer involves a much delayed decline, as compared with the drop after surgical excision, but one that remains very useful prognostically. Serial values in the Stanford series were stable after one year in 49 percent of the patients but were increasing again in 51 percent.[105, 106] Progressive reelevation of the values for prostate-specific antigen indicates either a failure of local treatment or the appearance of overt systemic metastases.

Residual Tumor

There has been a controversy for several years about the importance of residual cancer after radiation therapy. Systematic biopsies of fully treated patients have shown a 35 to 91 percent incidence of apparently viable tumor,[11, 86, 88, 106-111] and some centers have resorted to salvage surgery in such cases.[111] What is the clinical importance of residual tumor after radiation? The correlation of the presence of residual cancer after one year with the appearance of delayed distant metastases has been a source of concern.[106, 111] Progression to Stage D disease and mortality are both greatly increased in the subgroup of patients whose local disease seems to have resisted radiation therapy despite the absence of palpable local growth.[106]

TREATMENT OF STAGE C PROSTATIC CANCER

Overt Stage C disease, in which there is a large local lesion with extraprostatic extension, has previously been treated primarily by radiation therapy with the hope of a cure[86, 112] or by direct resort to palliative hormonal therapy.[104] The hope of a surgical cure was only tentatively espoused by a few, because of the likelihood (over 50 percent) of positive pelvic nodes and the probability of leaving residual extraprostatic tumor.[113]

Recent reassessment of the results of radiation therapy with ultrasound examination and measurement of levels of prostate-specific antigen has shed new light on the question. The survival curves were identical for patients treated initially with hormonal therapy and for those treated first with radiation and then with hormonal therapy at the time of regression.

Since more accurate staging by ultrasound examination and prostate-specific-antigen determination is now available, a prospective study for the optimal management of Stage C disease is indicated.[106] For the present, early antitestosterone therapy may be the least harmful and most cost-effective treatment.[104]

TREATMENT OF METASTATIC CANCER

It has been more than 50 years since the effectiveness of withdrawal of androgens was demonstrated in the control of prostatic cancer.[1,2] The basic physiologic features of the androgen receptor and the biochemical pathway for hormonal dependence are only now being elucidated.

For many decades, two pathways have been recognized for the production of androgens in the mammalian body. The first and primary pathway occurs in the testes, with their production of testosterone. It is well known that normal prostatic tissue and most prostatic cancers respond to testosterone after it has been converted in the cytoplasm to dihydrotestosterone by 5α-reductase.[3,4] The second pathway of androgen production is found in the adrenal cortex. Relatively large quantities of androsterodione and dehydroepiandrosterone are produced there and are considered to provide about 5 percent of the androgenic stimulation available to the prostate or to prostatic cancer.[5,6] The current array of hormonal-treatment regimens can be divided into those that are designed as antitestosterone therapy and those that include added effects against adrenal androgens in order to attempt a total androgen blockade.

Antitestosterone therapy

Bilateral orchiectomy has been used worldwide as the most definitive and effective antitestosterone measure. This procedure can be performed in an outpatient setting with the patient under local anesthesia with minimal mortality.[7,8] Estrogen preparations have also been used for many decades, and their antitestosterone mechanism is well understood. They inhibit the secretion of pituitary luteinizing hormone to such a point that the circulating testosterone is essentially at castrate levels. Concern about the side effects of estrogens increased when it was demonstrated that they could alter platelet adhesiveness and increase the incidence of thromboembolic phenomena in patients treated for prostatic cancer.[9,10,11,12] Because of this concern, daily doses of diethystilbestrol were reduced in practice to 3 mg per day. Doses of 1 mg per day were also advocated and widely used.[13,14] The 1-mg dose probably produces fewer side effects, but it suppresses testosterone to castrate levels in only 70 percent of patients,[15] whereas the 3-mg dose invariably produces complete suppression.

Although estrogen therapy has been partially replaced by either orchiectomy or the use of analogues to luteinizing-hormone—releasing hormone (LHRH), as described below, the main side effects of estrogen therapy can be attenuated, and the drugs remain useful. Gynecomastia, once very common, is now usually prevented by superficial radiation to the breast tissue as a dose of up to 15 Gy before the start of therapy.[16] Although no results from a controlled study have been reported, the platelet-aggregating effects of estrogens are managed in practice by the daily use of aspirin. Since most of the side effects of estrogens occur early in treatment,[12,16] patients with well-controlled prostatic cancer who take diethystilbestrol should not have this therapy stopped or changed prematurely. If side effects do appear, the dose of diethystilbestrol should be reduced to 1 mg a day, with monitoring of the levels of testosterone and prostate-specific antigen.[17]

The third principal alternative for antitestosterone therapy is the recently developed family of peptides that are analogues of hypothalamic LHRH. These synthetic peptides (leuprolide, buserelin, and goserelin) are administered by parenteral injection. Their mechanism of action is to occupy the receptors of LHRH in the pituitary, initially stimulating the release of luteinizing hormone and then blocking the subsequent stimulation of the receptors by the endogenous pulsatile secretion of luteinizing hormone.[18,19,20] Depot preparations are now available that require only monthly injection for castrate levels of testosterone to be achieved.[21,22,23] Hot flashes may occur, as with orchiectomy.

The advantage of the LHRH analogues is that they avoid both the trauma of orchiectomy and the side effects of estrogen therapy, including gynecomastia and increased platelet adhesiveness. The disadvantage of the newer medications is twofold. First, the preparations have the potential for rapid worsening of a patient's condition during the initial two weeks of paradoxical stimulation of testosterone release. The drugs are therefore contraindicated for use as the only medication in patients with painful involvement of the spinal column, in whom compression of the spinal cord, or even paraplegia, might develop. The initial flare-up can be avoided by the concomitant use of antiandrogens[24,25] or the concomitant temporary use of estrogens.[26] The second disadvantage of these depot peptides is their high cost—more than $300 a month for a single injection.

Controversy about total androgen blockade

The concept of adding a blockade of adrenal androgens to orchiectomy was advanced by Huggins and Scott decades ago and tested by the use of surgical adrenalectomy.[27,28,29] Synthetic antiandrogens have been available for the same purpose for an equally long time,[30,31,32,33] among them cyproterone acetate, nilutamide, flutamide, ketoconazole, and others with similar mechanisms. These drugs all act by competing with androgens at the receptor level in previously sensitive cells, normal or malignant. Now being tested is finasteride, a specific inhibitor of 5α-reductase that permits testosterone to be "spared" but blocks most effects of androgens on prostatic cells by preventing the formation of dihydrotestosterone.[34]

In the 1980s the concept of total androgen blockade was reintroduced.[35,36] A prospective multicenter study in the United States, combining an LHRH analogue with flutamide or placebo, suggested an advantage for the addition of flutamide[24] and led to its approval by the Food and Drug Administration for general use. But other studies of total blockade have failed to show any advantage. A recent Danish multicenter study combined a similar depot LHRH analogue (goserelin) with flutamide therapy and compared the results with those of orchiectomy in 264 patients.[37] There was no difference with respect to survival or median time to detectable progression. A Canadian study[38] of treatment with orchiectomy plus placebo as compared with orchiectomy plus antiandrogens in more than 200 patients showed no difference in the time to detected progression, but there was a longer median survival with total androgen blockade. Other studies recently reported from France[39] and Italy[40] and an international effort[41] also failed to support the supplementary use of antiandrogen therapy except to suppress the LHRH flare-up.

The controversial marginal advantage of total androgen blockade must be weighed against its side effects, especially diarrhea,[24,25] and its very high cost. The use of flutamide has added about $200 per month to the high cost of therapy with depot LHRH alone.

Chemotherapy for prostatic cancer

Nonhormonal chemotherapy has been of little value to date in treating prostatic cancer. Prospective controlled studies by the National Prostatic Cancer Project in the first of the 1980s gave no real encouragement for the use of available antimetabolites and cytotoxic agents. As reviewed by Eisenberger,[42] the terminal course of patients who have undergone after receiving hormonal therapy is measured in weeks despite chemotherapy. A caveat is that most candidates for chemotherapy, who have not responded to hormonal therapy, remain responsive to androgens. They are very likely to have severe, symptomatic exacerbations of their already terminal disease if their level of androgens is elevated again.[43,44] In practice, patients who have not undergone orchiectomy must not have their therapy with estrogen or LHRH stopped, and the addition of exogenous androgens must still be avoided.

FOOTNOTES

[1] Klein LA. Prostatic carcinoma. N Engl J Med 1979; 300:824-32.

[2] Silverberg E, Lubera JA. Cancer statistics, 1989. CA 1989; 39:3-20.

[3] Noble RL. The development of prostatic adenocarcinoma in Nb rats following prolonged sex hormone administration. Cancer Res 1977; 37:1927-31.

[4] Wilson JD, ed. Models for prostatic cancer. Vol. 37 of Progress in clinical and biological research. New York: Alan R. Liss, 1980.

[5] Yoshi MV, Prasanwila P, Graves S, et al. Expression of ras oncogene p21 in prostate cancer. N Engl J Med 1986; 314:133-7.

[6] Thompson TC, Southgate J, Kitchener G, Land H. Multistate carcinogenesis induced by ras and myc oncogenes in a reconstituted organ. Cell 1989; 56:917-26.

[7] Zaridze DO, Boyle P. Cancer of the prostate, epidemiology and etiology. Br J Urol 1987; 59:493-502.

[8] Ross RK, Paganini-Hill A, Henderson BE. Epidemiology of prostatic cancer. In: Skinner DG, Lieskovsky G, eds. Diagnosis and management of genitourinary cancer. Philadelphia: W.B. Saunders, 1988:48-8.

[9] Scott R Jr, Mulchaik DL, Lasakowski TZ, Schmalhorst WR. Carcinoma of the prostate in elderly men: incidence, growth characteristics and clinical significance. JAMA 1960; 101:902-7.

[10] Sheldon CA, Williams RD, Fraley EE. Incidental carcinoma of the prostate a review of the literature and critical reappraisal of classification. J Urol 1980; 124:826-31.

[11] Levine RL, Wilchinsky M. Adenocarcinoma of the prostate: a comparison of the disease in blacks versus whites. J Urol 1979; 121:781-2.

[12] Daval EB, Protissar L, Dahlberg S. Race, socioeconomic status, and other prognostic factors for survival from prostate cancer. J Natl Cancer Inst 1985; 74:1001-6.

[13] Yatani R, Chigusa K, Akazaki K, Stemmermann GN, Welsh RA, Correa P. Geographic pathology of latent prostatic carcinoma. Int J Cancer 1982; 29:611-4.

[14] Gerlevgarde JM, Johnsen WD, Welsh RA, Akazaki K, Correa P. Prevalence of latent prostate carcinoma in two U.S. populations. J Natl Cancer Inst 1980; 65:371-6.

[15] Ross RK, Bernstein L, Judd H, Hanisch R, Pike M, Henderson B. Serum testosterone levels in healthy young black and white men. J Natl Cancer Inst 1986; 76:45-8.

[16] Hill PB, Wynder EL. Effect of a vegetarian diet on dexamethasone on plasma prolactin, testosterone and dehydroepiandrosterone in men and women. Cancer Lett 1979; 7:273-82.

[17] Eisenberg OD, Carter BS, Beaty TL, Childs B, Walsh PC. The familial aggregation of prostate cancer: a case control study. J Urol 1990; 143:31A, abstract.

[18] Kabalin JN, McNeal JE, Price HM, Freiha FE, Stamey TA. Unsuspected adenocarcinoma of the prostate in patients undergoing cystoprostatectomy for other causes: incidence, histology and morphometric observations. J Urol 1989; 141:1091-4.

[19] McNeal JE, Bostwick DG, Kindrachuk RA, Redwine EA, Freiha FS, Stamey TA. Patterns of progression in prostate cancer. Lancet 1988; 1:60-3.

[20] McNeal JE, Redwine EA, Freiha FS, Stamey TA. Zonal distribution of prostatic adenocarcinoma: correlation with histologic pattern and direction of spread. Am J Surg Pathol 1988; 12:897-906.

[21] Byar DP, Mostofi FK. Carcinoma of the prostate: prognostic evaluation of certain pathologic features in 208 radical prostatectomies examined by the step-section technique. Cancer 1972; 30:5-13.

[22] Stamey TA, McNeal JE, Freiha FS, Redwine E. Morphometric and clinical studies on 68 consecutive radical prostatectomies. J Urol 1988; 139:1235-41.

[23] Villers A, McNeal JE, Redwine E, Freiha FS, Stamey TA. The role of perineural space invasion in the local spread of prostate adenocarcinoma. J Urol 1989; 142:763-8.

[24] Fowler JE Jr, Whitmore WF Jr. The incidence and extent of pelvic lymph node metastases in apparently localized prostate cancer. Cancer 1981; 47:2941-5.

[25] Saitoh H, Hida M, Shimbo T, Nakamura K, Yamagata J, Saitoh T. Metastatic patterns of prostatic cancer: correlation between sites and number of organs involved. Cancer 1984; 54:3078-84.

[26] Chodak GW, Keller P, Schoenberg HW. Assessment of screening for prostatic cancer using digital rectal examination. J Urol 1989; 141:1136-8.

[27] Lee F, Torp-Pedersen S, Littrup PJ, et al. Hypoechoic lesions of the prostate: clinical relevance of tumor size, digital rectal examination, and prostate-specific antigen. Radiology 1989; 170:29-32.

[28] Hodge K, McNeal JE, Terris MK, Stamey TA. Random systematic versus directed ultrasound guided transrectal core biopsies of the prostate. J Urol 1989; 141:71-4.

[29] Hodge KK, McNeal JE, Stamey TA. Ultrasound guided transrectal core biopsies of the palpably abnormal prostate. J Urol 1989; 142:66-70.

[30] Scardino PT. Early detection of prostate cancer. Urol Clin North Am 1989; 16:635-45.

[31] Chodak GW, Bibbo M, Sumas FH II, Wied GL. Transrectal aspiration versus transperineal core biopsy for the diagnosis of carcinoma of the prostate. J Urol 1984; 132:480-2.

[32] Benson MC. Fine-needle aspiration of the prostate. In NCI monographs. No. 7. Washington, D.C.: Government Printing Office, 1988:19-34. (NIH publication no. 88-3005.)

[33] Ragde H, Aldape HC, Bagley CM Jr. Ultrasound-guided prostate biopsy: Biopty gun superior to aspiration. Urology 1988; 32:503-6.

[34] Kaye KW, Horwitz CA. Transrectal ultrasound-guided prostate biopsies using new automatic gun: analysis of 100 consecutive cases. J Endourol 1989; 3:155-62.

[35] Lee F, Littrup PJ, Torp-Pedersen ST, et al. Prostate cancer: comparison of transrectal US and digital rectal examination for screening. Radiology 1988; 168:389-94.

[36] Nesbitt JA, Drago JR, Badalament RA. Transrectal ultrasonography: early experience with use as prostate cancer detection tool. Urology 1988; 34:120-2.

[37] Cooner WH, Mosley BR, Rutherford CL Jr, et al. Clinical application of transrectal ultrasonography and prostate specific antigen in the search for prostate cancer. J Urol 1988; 139:758-61.

[38] Ragde H, Bagley CM Jr, Aldape HC, Bisako JC. Screening for prostate cancer with high-resolution ultrasound. J Endourol 1989; 3:115-24.

[39] Muldoon L, Resnick MI. Results of ultrasonography of the prostate. Urol Clin North Am 1989; 16:893-702.

[40] Perrin P, Mouriquand P, Moreaillies M, Oukhelfa H, Maquet JH, Devonec M. Hypothetical place of transrectal ultrasound in the diagnosis of prostatic cancer at an early stage. J Endourol 1989; 3:109-14.

[41] Chodak GW. Screening for prostate cancer: role of ultrasonography. Urol Clin North Am 1989; 16:857-61.

[42] Stamey TA. Prostate cancer: some basic clinical and morphometric observations. Urology Monogr 1989; 10:79-91.

[43] Wang MC, Valenzuela LA, Murphy GP, Chu TM. Purification of a human prostate specific antigen. Invest Urol 1979; 17:159-63.

[44] Ford TF, Butcher DN, Masters JR, Parkinson MC. Immunocytochemical localisation of prostate-specific antigen: specificity and application to clinical practice. Br J Urol 1985; 57:50-5.

[45] Hortin GL, Bahnson RR, Dahl M, Chan K-M, Catalona WJ, Anderson JH. Differences in values obtained with 3 assays of prostate specific antigen. J Urol 1988; 139:782-5

[46] Chan DW, Bruzek DJ, Oesterling JE, Rock RC, Walsh PC. Prostate-specific antigen as a marker for prostatic cancer: a monoclonal and a polyclonal immunoassay compared. Clin Chem 1987; 33:1916-20

[47] Stamey TA, Yang N, Hay AR, McNeal JE, Freiha FS, Redwine E. Prostate-specific antigen as a serum marker for adenocarcinoma of the prostate. N Engl J Med 1987; 317:909-16.

[48] Gittes RF. Prostate-specific antigen. N Engl J Med 1987; 317:954-6.

[49] Stamey TA. Prostate-specific antigen in the diagnosis and treatment of adenocarcinoma of the prostate. Urology Monogr 1989; 10:50-64.

[50] Lange PH, Brawer MK. Serum prostate-specific antigen: its use in diagnosis and management of prostate cancer. Urology 1989; 33:Suppl 8:13-7.

[51] Hudson MA, Bahnson RR, Catalona WJ. Clinical use of prostate specific antigen in patients with prostate cancer. J Urol 1989; 142:1011-7.

[52] Brawer MK, Schifman RB, Ahmann FR, Ahmann MC, Coulis KM. The effect of digital rectal examination on serum levels of prostate-specific antigen. Arch Pathol Lab Med 1988; 112:1110-2.

[53] Dalton DL. Elevated serum prostate-specific antigen due to acute bacterial prostatitis. Urology 1989; 33:465.

[54] Stamey TA, Kabalin JN. Prostate-specific antigen in the diagnosis and treatment of adenocarcinoma of the prostate. I. Untreated patients. J Urol 1989; 141:1070-6.

[55] Schnall MD, Lenkinski RE, Pollack HM, Imai Y, Kressel HY. Prostate: MR imaging with an endorectal surface coil. Radiology 1989; 172:570-4.

[56] Mostofi FK. Grading of prostatic carcinoma. Cancer Chemother Rep 1975; 59:111-7.

[57] Epstein JI, Berry SJ, Eggleston JC. Nuclear roundness factor: a predictor of progression in untreated Stage A2 prostate cancer. Cancer 1984; 54:1668-71.

[58] Gleason DF. The Veterans Administration Cooperative Urologic Research Group: histologic grading and clinical staging of prostatic carcinoma. In: Tannenbaum M, ed. Urologic pathology: the prostate. Philadelphia: Lea & Febiger, 1977:171-98.

[59] Oesta JF, Englander LC, Murphy GP. Comparative evaluation of National Prostatic Cancer Treatment Group and Gleason systems for pathologic grading of primary prostatic cancer. Urology 1986; 27:306-8.

[60] Paulson D, Piserchia PV, Gardner W. Predictors of lymphatic spread in prostatic adenocarcinoma: uro-oncology research group study. J Urol 1980; 123:897-9

[61] Oesterling JE, Brendler CB, Epstein JI, Kimball AW Jr, Walsh PC. Correlation of clinical stage, serum prostatic acid phosphatase and preoperative Gleason grade with final pathologic stage in 275 patients with clinically localized adenocarcinoma of the prostate. J Urol 1987; 138:92-8.

[62] Alihoff EP, Proppe KH, Chapman CM, Lin C-H, Prout GR Jr. Evaluation of prostatic specific acid phosphatase and prostate specific antigen in identification of prostatic cancer. J Urol 1983; 129:315-8.

[63] Hricak H. Noninvasive imaging for staging of prostate cancer: magnetic resonance imaging, computed tomography, and ultrasound. In: NCI monographs. No. 7. Washington, D.C.: Government Printing Office, 1988:81-8. (NIH publication no. 88-3008.)

[64] Scardino PT, Shinohara K, Wheeler TM, Carter SS. Staging of prostate cancer: value of ultrasonography. Urol Clin North Am 1989; 16:713-34.

[65] Middleton RG. Value of and indications for pelvic lymph node dissection in the staging of prostate cancer. In: NCI monographs. No. 7. Washington, D.C.: Government Printing Office, 1988:41-3. (NIH publication no. 88-3005.)

[66] Gervasi LA, Mata J, Easley JD, et al. Prognostic significance of lymph nodal metastases in prostatic cancer. J Urol 1988; 140:333-8

[67] Smith JA Jr, Cho Y-H. Management of stage A prostate cancer. Urol Clin North Am 1990; 17:789-97.

[68] Lange PH. Controversies in management of apparently localised cancer of the prostate. Urology 1989; 34:Suppl 4:13-8.

[69] Paulson DF. Randomized series of treatment with surgery versus radiation for prostate adenocarcinoma. In: NCI monographs. No. 7. Washington, D.C.: Government Printing Office, 1988:137-21 (NIH publication no. 88-3005.)

[70] Bagshaw MA, Cox RS, Ray GR. Status of radiation treatment of prostatic cancer at Stanford University. In: NCI monographs. No. 7. Washington, D.C.: Government Printing Office, 1988:47-60. (NIH publication no. 88-3006.)

[71] Blute ML, Naito A, Zincke H, Farrow GM, Therneau T, Lieber MM. Pattern of failure after radical retropubic prostatectomy for clinical y and pathologically localized adenocarcinoma of the prostate influence of tumor deoxyribonucleic acid ploidy. J Urol 1989; 142:1263-5

[72] Gibbons RP, Tidrick RT. Radical prostatectomy for clinically localized prostate cancer: long-term surgical results and current morbidity. In: NCI monographs. No. 7. Washington, D.C.: Government Printing Office, 1988:133-6 (NIH publication no. 88-3005.)

[73] Lepor H, Walsh PC. Long-term results of radical prostatectomy in clinically localized prostate cancer: experience at The Johns Hopkins Hospital. In: NCI monographs. No. 7. Washington, D.C: Government Printing Office, 1988:117-23 (NIH publication no. 88-3005.)

[74] Walsh PC, Donker PJ. Impotence following radical prostatectomy: insight into etiology and prevention. J Urol 1982; 128:492-7

[75] Walsh PC. Radical retropubic prostatectomy with reduced morbidity: an anatomic approach. In: NCI monographs No. 7 Washington D.C Government Printing Office, 1988:133-7. (NIH publication no. 88-3005.)

[76] Walsh PC, Epstein JI, Lowe FC. Potency following radical prostatectomy with wide unilateral excision of the neurovascular bundle. J Urol 1987; 138:823-7

[77] Reiner WG, Walsh PC. An anatomical approach to the surgical management of the dorsal vein and Santorini's plexus during radical retropubic surgery. J Urol 1979; 121:198-200

[78] Peters CA, Walsh PC. Blood transfusion and anesthetic practices in radical retropubic prostatectomy. J Urol 1985; 134:81-3.

[79] Zincke H. Extended experience with surgical treatment of Stage D1 adenocarcinoma of the prostate: significant improvement of immediate adjuvant hormonal treatment (orchiectomy) on outcome. Urology 1988; 33:Suppl 5:27-38

[80] Bigg SW, Catalona WJ. Advisability of performing nerve-sparing radical prostatectomy for stage B2 prostate cancer. J Urol 1989; 141:345A abstract

[81] Stamey TA, Freiha FS. The Stanford radical retropubic prostatectomy (RRP). J Urol 1990; 143:213A abstract.

[82] O'Donnell P, Finan BF. Continence following nerve-sparing radical prostatectomy. J Urol 1989; 142:1227-9.

[83] Basinger GT, Gittes RF. Lymphocyst ultrasound diagnosis and urologic management. J Urol 1975; 114:740-8.

[84] Borgni PC, Watson RC, Whitmore WF Jr. Lymphocele after pelvic lymphadenectomy for urologic cancer. Urology 1981; 17:29-43.

[85] Krane RJ, Goldstein I, de Tejada IS. Impotence. N Engl J Med 1989; 321:1648-59.

[86] Stamey TA, Kabalin JN, McNeal JE, et al. Prostate specific antigen in the diagnosis and treatment of adenocarcinoma of the prostate. II. Radical prostatectomy treated patients. J Urol 1989; 141:1076-83.

[87] Borgnino WF Jr, Hilaris BS, Grabstald H. Retropubic implantation to I[125] in the treatment of prostate cancer. J Urol 1972; 108:918-20.

[88] Carlton CE Jr, Hudgins PT, Guerriero WG, et al. Radiotherapy in the management of stage C carcinoma of the prostate. J Urol 1978; 119:206-10.

[89] Schellhammer PF, el-Mahdi AM, Higgins EM, Schulhafer EP, Ladaga LE, Babb TJ. Prostate biopsy after definitive treatment by interstitial [125]iodine implant or external beam radiation therapy. J Urol 1987; 137:897-901.

[90] Grado GL, Wheeler TM. Local control of prostate cancer with radiotherapy: frequency and prognostic significance of positive results of postirradiation prostate biopsy. In: NCI monographs. No. 7. Washington, DC.: Government Printing Office, 1988:85-103. (NIH publication no. 88-3005.)

[91] Paulson DF, Herr HW, Moore MJ, Russo P, Sogani PC, Whitmore WF Jr. Early experience with 100 radical retropubic prostatectomies and interstitial [125]iodine the MSKCC experience. J Urol 1989; 142:338A abstract.

[92] Snyder P, Lytton B [125]seen implant for prostate cancer: a 10 year followup. J Urol 1989; 143:309A abstract.

[93] Holm HH, Juul N, Pedersen JF, Rasmen H, Stryer I, Transperineal [125]seed implantation in prostate cancer guided by transrectal ultrasonography. J Urol 1983; 130:283-6

[94] Loening SA, Elson ED. Percutaneous transperineal placement of radioactive gold seeds for treatment of localized prostatic carcinoma. J Endourol 1989; 23:301-9.

[95] Carter SS, Torp-Pedersen ST, Holm HH. Ultrasound guided implantation technique in the treatment of prostatic cancer. Urol Clin North Am 1989; 16:751-63.

[96] Bagshaw MA, Kaplan HS, Saegerman RH. Linear accelerator supervoltage radiotherapy. VII carcinoma of the prostate. Radiology 1965; 85:131-9.

[97] Shipley WU, Prout GR Jr, Coachman NM, et al. Radiation therapy for localized prostate carcinoma: experience at the Massachusetts General Hospital (1973-1981). In: NCI monographs. No. 7. Washington, D.C.: Government Printing Office, 1988:87-93. (NIH publication no. 88-3005.)

[98] Laramore GE, Krall JM, Thomas FJ, Griffin TW, Maor MH, Hendrickson FR. Fast neutron radiotherapy for locally advanced prostatic cancer: results of an RTOG randomized study. Int J Radiat Oncol Biol Phys 1985; 11:1931-7.

[99] Pilepich MV. Radiation Therapy Oncology Group studies in carcinoma of the prostate. In: NCI monographs. Washington, D.C.: Government Printing Office, 1988:81-8. (NIH publication no. 88-3005.)

[100] Asbell SO, Krall JM, Pilepich MV, et al. Elective pelvic irradiation in stage A- B carcinoma of the prostate: analysis of RTOG 77-06. Int J Radiat Oncol Biol Phys 1982; 15:1307-16

[101] Hanks GE. External-beam radiation therapy for clinically localized prostate cancer. Patterns of Care Studies. In: Urban JPG, Waters JH: NCI monographs No. 7. Washington, D.C.: Government Printing Office, 1988:75-84. (NIH publication no 88-3005.)

[102] Goldstein I, Feldman MI, Deckers PJ, Babayan RK, Krane RJ. Radiation-associated impotence a clinical study of its mechanism. JAMA 1984; 251:903-10

[103] Stamey TA, Kabalin JN, Ferrari M. Prostate specific antigen in the diagnosis and treatment of adenocarcinoma of the prostate. II. Radiation treated patients. J Urol 1989; 141:1084-7.

[104] Kabalin JN, Hodge KK, McNeal JE, Freiha FS, Stamey TA. Identification of cancer in the prostate following radiation therapy: role of transrectal ultrasound guided biopsy and prostate specific antigen. J Urol 1989; 142:326-31

[105] Carter SS, Wheeler TM, Scardino PT. Ultrasonographic changes in the normal and malignant prostate after definitive radiotherapy. Urol Clin North Am 1987; 14:741-9

[106] Nachtsheim DA Jr, McAninch JW, Stultzman RE, Goebel JL. Latent residual tumor following external radiotherapy for prostate adenocarcinoma. J Urol 1978; 120:313-4

[107] Herr HW, Whitmore WF Jr. Significance of prostatic biopsies after radiation therapy for carcinoma of the prostate. Prostate 1982; 3:339-50.

[108] Freiha FS, Bagshaw MA. Carcinoma of the prostate: results of post-irradiation biopsy Prostate 1984; 5:19-23

[109] Scardino PT, Frankel JF, Wheeler TM, et al. The prognostic significance of post-irradiation biopsy results in patients with prostatic cancer. J Urol 1988; 135:510-8

[110] Kiesling VJ, McAninch JW, Goebel JL, Agee RE. External beam radiotherapy for adenocarcinoma of the prostate: a clinical follow up J Urol 1980; 136:851-4

[111] Leach GE, Cooper JK, Kagan AR, Snyder R, Forsythe R. Radiotherapy for prostatic carcinoma post-irradiation prostatic biopsy and recurrence patterns with long-term follow up J Urol 1983; 128:503-9

[112] Neerhut GJ, Wheeler T, Cantini M, Scardino PT. Salvage radical prostatectomy for radiorecurrent adenocarcinoma of the prostate J Urol 1988; 140:544-9

[113] Hanks GE Treatment of locally advanced prostate cancer with radiation therapy. Urology 1989; 33:Suool 5:37-41

[114] Byar DP, Corle DK. Hormone therapy for prostate cancer: results of the Veterans Administration Cooperative Urological Research Group studies. In: NCI monographs No 7. Washington, D.C.: Government Printing Office, 1988:168-70. (NIH publication no 88-3005.)

[115] McCullough DG, Leadbetter WF. Radical pelvic surgery for locally extensive carcinoma of the prostate J Urol 1973; 108:939-43.

[116] Schroeder FH, Belt E. Carcinoma of the prostate: a study of 313 patients with stage C tumors treated by total perineal prostatectomy? J Urol

[117] Zincke H, Utz DC, Taylor WF. Bilateral pelvic lymphadenectomy and radical prostatectomy for clinical stage C prostatic cancer: role of adjuvant treatment for residual cancer and in disease progression. J Urol 1986; 135:1198-205.

[118] Paulson DF, Cline WA Jr, Koefoot RB Jr, Hinshaw W, Stephani S. Extended field radiation therapy versus delayed hormonal therapy in node positive prostatic adenocarcinoma. J Urol 1982; 127:935-7.

[119] Paulson B, Williams RD. Current options in the management of clinical stage C prostatic carcinoma. urol Clin North Am 1990; 17:853-66.

[120] Huggins C, Hodges CV. Studies on prostatic cancer. I. The effect of castration, of estrogen and of androgen injection on serum phosphatases in metastatic carcinoma of the prostate. Cancer Res 1941; 1:293-7.

[121] Walsh PC Physiologic basis for hormonal therapy in carcinoma of the prostate Urol Clin North Am 1875; 3:135-40.

[122] Glenn JF Suberpididymal orchiectomy. an acceptable alternative J urol 1990; 144:643-4.

[123] de Voogt HJ, Smith PH, Pavone-Macaluso M, de Pauw M, Suciu S. Cardiovascular side effects of diethylstilbestrol, cyproterone acetate, medroxyprogesterone acetate and estramustine phosphate used for the treatment of advanced prostatic cancer: results from European Organization for Research on Treatment of Cancer trials 30761 and 30763 J Urol 1986; 135:303-7.

[124] Shearer RJ, Hendry WF, Sommerville IF, Perrjauson JD. Plasma testosterone an accurate monitor of hormonal treatment in prostatic cancer. Br J Urol 1973; 45:668-77

[125] Gagmon JD, Moss WT Stevens KR. Pre-estrogen breast irradiation for patients with carcinoma of the prostate. a critical review. J Urol 1974; 111:183-4

[126] The Veterans Administration Cooperative Urological Research Group Carcinoma of the prostate treatment comparisons J Urol 1967; 98:516-23.

[127] Stamey TA, Kabalin JN, Perrari M, Yang N. Prostate specific antigen in the diagnosis and treatment of adenocarcinoma of the prostate IV. Antiandrogen treated patients J Urol 1989; 141:1088-92.

[128] Schally AV, Arimura A, Baba Y, et al. Isolation and properties of the PSH and LH releasing hormone Biochem Biophys Res Commun 1971; 43:393-9

[129] Schally AV, Redding TW, Comaru-Schally AM. Inhibition of prostatic tumors by synthetic and antagonistic analogs of LH-RH. Prostate 1983; 4:545-52

[130] The Leuprolide Study Group. Leuprolide versus diethylstilbestrol for metastatic prostate cancer. N Engl J Med 1984; 311:1281-6

[131] Idem. Clinical study of depot leuprolide in the treatment of advanced prostate cancer. J Urol 1988; 141:348A abstract.

[132] Blackledge G, Emtage LA, Trethowan C, et al. "Zoladex" depot vs DES 3 mg/day in advanced prostate cancer, a randomized trial comparing efficacy and tolerability. J Urol 1989; 141:347a. abstract.

[133] Kuhn J-M, Billebaud T, Navratil H, et al. Prevention of the transient adverse effects of a gonadotropin-releasing hormone analogue (buserelin) in metastatic prostate carcinoma by administration of an antiandrogen (nilutamide). N Engl J Med 1989; 321:413-6

[134] Stein BS, Smith JA Jr. DES lead-in to use of luteinizing hormone releasing hormone analog in treatment of metastatic carcinoma of prostate. Urology 1985; 25:350-3

[135] Huggins CE, Scott WW. Bilateral adrenalectomy in prostatic cancer clinical features and urinary excretion of 17-ketosteroids and estrogen. Ann Surg 1945; 122:1031-41.

[136] Scott WW, Menon M, Walsh PC. Hormonal therapy of prostatic cancer. Cancer 1980; 45:Suppl 7:1939-58

[137] Walsh PC, Gittes RF. Inhibition of extratesticular stimuli to prostatic growth in the castrate rat by antiandrogens Endocrinology 1970; 87:624-7.

[138] Pavone Macaluso M, Smith PH, Sarosdy V, Dariello G. Antiandrogens alone or in combination for treatment of prostate cancer: the European experience. Urology 1986; 34:Suppl 5:27-34.

[139] McConnell JD. Androgen ablation and blockade in the treatment of benign prostatic hyperplasia. Urol Clin North Am 1987; 14:763-70.

[140] Labrie F, Dupont A, Belanger A, et al. New hormonal therapy in prostatic carcinoma. combined treatment with an LHRH agonist and an antiandrogen. Clin Invest Med 1982; 5:267-78.

[141] Idem. New hormonal treatment in cancer of the prostate combined administration of an LHRH agonist and antiandrogen J Steroid Biochem 1983; 19:999-1007.

[142] Crawford ED, Eisenberger MA, McLeod DG, et al. A controlled trial of leuprolide with and without flutamide in prostatic carcinoma. N Engl J Med 1989; 321:419-24

[143] Inversen P, Wolf H, Hvidt V, Karup T, Rasmussen F, Danish Prostate Cancer Group. Zoladex plus flutamide vs orchiectomy in the treatment of advanced prostatic cancer J Urol 1989; 141:348A. abstract.

[144] Trachtenberg J, Beland G, Elhilali MM, et al. A randomized trial of total androgen ablation vrs orchiectomy in patients with metastatic prostatic cancer J Urol 1989; 141:347A abstract.

[145] Fourrade RO, Carlou G, Chibby P, et al. Total androgen blockade in advanced prostatic carcinoma interim report of a double blind study using Zoladex and Flutamide J Urol 1990; 143:320A. abstract

[146] De Silverio P, Berlo M, Costantini A. The use of the LHRH analogue goserelin alone or in combination with the antiandrogen cyproterone acetate in the treatment of advanced prostatic carcinoma. an Italian multicentric trial. J Urol 1990; 143:306A abstract.

[147] Holdaway I, Altwein JE, Kloppel KP, Laufmayr G, Tyrrell CJ, Vanrenhorst E. A multicentre randomised trial comparing the LERR agonist "Zoladex" with "Zoladex" in combination with Flutamide in the treatment of advanced prostate cancer. J Urol 1990; 143:230A. abstract.

[148] Eisenberger MA. Chemotherapy for prostate carcinoma. In: NCI monographs. No. 7. Washington, D.C.: Government Printing Office, 1988:151-63. (NIH publication no. 88-3005.

[149] Manni A, Santen RJ, Boucher AE, et al. Androgen priming and response to chemotherapy in advanced prostatic cancer J Urol 1984; 134:1243-6.

[150] Fowler JE Jr, Whitmore WF Jr. The response of metastatic adenocarcinoma of the prostate to exogenous testosterone. J Urol 1981; 128:373-5.

The CHAIRMAN. Thank you very much, Senator Stevens.

Your prostate cancer was detected through a routine physical, which detected the disease in its earliest stage, unfortunately, our other colleague Senator Cranston's was detected at a more advanced stage, indeed he points out that he did not get his routine physical in 1989. So as you point out, early detection is really enormously important.

Do you find that some people are almost reluctant to find out whether they have prostate cancer because they fear the treatment? What do you think—is this lethargy of people really wanting to find out whether they may or may not have it? As I understand—and I stand perhaps to be corrected—but the prospects of having prostate cancer increase significantly with age, and the chances of men 75 or 80 years of age or older having prostate cancer are well beyond 50 percent or even higher. I'm just wondering what you think is the general reticence or reluctance of people as they get older to get a physical with rectal examination: The preventive steps which you clearly took and which have made a very important difference, I imagine, in terms of your own life, are too often ignored by many men.

Senator STEVENS. Senator, I find the older men get, the more they know about prostate cancer, the more willing they are to have the examinations that might detect it. The great difficulty is that if they had had similar examinations early in their lives, they could have had the detection and the cure that is possible, and through some very simple means, really.

I am of the opinion that since it is a cancer that deals primarily with older men, it really just doesn't get the kind of publicity that other cancers do. But my experience with this led me to go into a lot of cancer statistics for men. There are other cancers—cancer of the testes, cancer of the penis, cancer of the male genital system—they are all increasing in numbers. And I think the real problem is just that American men have a great antipathy for annual physicals.

My own father-in-law passed away with cancer, and I discovered he hadn't had a physical since he got out of the Navy in World War II. He was a robust man, very healthy, very athletic; he just didn't believe in going to see doctors. And that is one of the messages that Senator Cranston and I are trying to convey, and that is that American men, particularly after age 40, ought to see a doctor at least once a year, and if they do, they'll have a chance of having a much healthier life and have greatly reduced health costs throughout their lives.

The CHAIRMAN. Could you just comment briefly on the treatment? What can you tell us that could be reassuring in terms of the treatment? Obviously, you've had a successful experience with it. Is it something that ought to be feared; or is it something that is extraordinary in terms of discomfort? What could you tell us?

Senator STEVENS. No. As a matter of fact, I had a call from a foreign ambassador to the United States who was going to have the same operation I had, and he was greatly in fear of it primarily, I think, because he was a foreigner in our country and really didn't quite understand some of the things he was being told.

My symptoms were discovered at least 2 years before I did have the operation. We watched it through annual physicals, and when it reached the point where my doctor told me he thought it was continuing to expand, I had different tests. In the last 2 years, there have been new tests that have been perfected—the prostate specific antigen, which is a blood test that does increase in its level as the cancer starts to spread. And then there is the transrectal ultrasound concept that now gives the additional test to prove whether the cancer is there, along with the improved capability to detect cancer through biopsy of the cancer.

The operation itself that I elected was the complete removal of the prostate gland, and I've got to tell you, Senator, I was out of bed the next morning and was out of the hospital in 7 days and back at work in 3 weeks, and I'm happy to say I am now back playing three sets of tennis in the morning before I come to work. So it is a trip that is well worthwhile, and it is nothing to fear.

I am amazed how many men really do fear it and elect other treatments that are less successful because of that fear. But I've got to tell you that I really believe that the concept of detection and treatment and reliance upon a physician is essential. And I also believe, as my doctor did, in getting a second opinion. He insisted that I get a second opinion before we go ahead with the surgery, and that was a very successful concept and did convince me that it was necessary to move and move quickly.

The problem with cancer of the prostate is that many men will live with it and not die of it; other men will have cancer, and it will start to spread, and it will expand beyond the capsule which contains the prostate, and when that happens they will have metastasized, and they will have cancer of other organs, and it will be very difficult to treat.

So it is a subjective cancer and one that needs to be given subjective consideration in every, single man and through the concept of trying to keep informed as to whether there is a problem, and if there is a problem, pursue it with the advancing technology today.

Senator, I think within the last two and a half years the technology for dealing with prostate cancer has come as far as it did in the whole preceding time of our medical history in the United States.

The CHAIRMAN. Just on that point, you mentioned some of the ways to detect prostate cancer. One of the features of our legislation is to try and get these successful procedures out into the field at the earliest possible time, which I think is always important and is certainly important in this particular disease.

You have been wonderful to share this experience with us. We know it was difficult but your success and testimony about the positive aspects of early detection is inspiring. I think Americans who hear you and listen to you hopefully will be inspired to take the kinds of steps that you did and to follow that course, and that can make a very, very important and powerful difference in their lives and the lives of the people they care deeply about.

Senator Wellstone.

OPENING STATEMENT OF SENATOR WELLSTONE

Senator WELLSTONE. Thank you, Mr. Chairman.

First of all, I want to apologize to Senator Stevens for missing his testimony. I did want to start out with a brief story and then ask one question and make one observation.

Senator Stevens and I were once riding the train together—I don't know if you remember this or not, Ted—and he turned to me, and he said, "You know, some people, they keep all that emotion inside of them. You and I, we let it all out. We're going to live a long time." And I am delighted to hear about your clean bill of health and certainly know that you will live along time. And I think it is really quite courageous of you to step forward and to testify and to speak out. I think it provides a lot of inspiration to other people.

I have just two questions. One is—and if you've already covered this, Senator Stevens, I apologize—but did you have to overcome some of your own hesitation with the symptoms of actually going to the doctor? Did you have fear about this, and what was that fear, and what did you have to overcome in terms of your own personal decisionmaking?

Senator STEVENS. Senator, I'm going to be the million dollar man. I have had an appendectomy, a hernia operation and a gall bladder operation. I am probably unique in the sense that I have no fear of surgery, and in each instance it has been very successful for me. So when first my doctor and then the surgeon said that they thought an operation was essential, I readily concurred, and I'm glad I did, because I'm convinced that if it had gone on—as a matter of fact, I had not told you this, but the pathology indicated that had I waited even a few more months, it would have been too late. They can tell you that, and we had a second opinion on that, too; I had it checked a second time just to make sure because I think that is essential in the message I'm trying to convey. Prostate cancer is a subjective cancer. You cannot indicate how fast it is going to grow in any particular man, and for that reason it is essential if you have an indication that you might be developing some problem with the prostate that you follow through.

There are other procedures very early on that can deal with the growth of and expansion of a prostate that could very easily prevent cancer in and of themselves. So I think that it is essential to have those checks. And as I said before you came, I think it is essential for every man to have an annual physical once a year after he is 40, and I think we should make sure we've got the funds for those who cannot afford them otherwise to have that kind of care. I think that is essential for all of us.

Senator WELLSTONE. I was going to ask you whether you had any sense, not necessarily in terms of statistics, of how much of the problem of men not stepping forward has to do with just not being real attuned to what you need to do for your own health care, as opposed to people facing the financial barriers. And it sounds to me like one of the things you are saying is that we have to make sure that people do have the resources to be able to have these physical exams, because the preventive part is the difference between life and death, if I understand you. Is that correct?

Senator STEVENS. It is. As a matter of fact, as I have learned since I've been through this, the impact upon black men in America is staggering. I have not mentioned one thing, Paul, and that is

we are told once we come through this that we should tell our sons that they have a higher risk of prostate cancer than the sons of men who do not have prostate cancer. I had the unfortunate task of writing to my sons and telling them and urging them to have their annual physicals and have the observation necessary because of this advice that I have received. And that has got to be a staggering duty to the black men of the United States because, as I said, they have a 50 percent higher rate of prostate cancer than the nonblack males in this country.

It is something that raises some interesting environmental aspects because of the differences. That is why Senator Cranston and I and those in the House who have been involved in it and throughout the country are speaking out about the whole concept of research now, because this is a cancer that I am convinced is an environmental cancer; that there must be something in our society that causes us to have such higher instance of prostate cancer than men through the world.

Senator WELLSTONE. Mr. Chairman, my last point is that I want to say for the record that one of the things that I've learned in my first year here is that you meet people who you don't necessarily agree with on every issue but you come to really like and respect, and I'd put Senator Stevens at the top of the list, and I really mean that. I'm just so delighted that you're here and that you've said what you said. I think it is really important.

And my observation would be that those of us in the Senate are fortunate enough that we have the health care coverage, that we can get the best medical care, that we have a doctor like a Dr. Krasner who can encourage us and make sure that we go through the annual physicals. And I think that's what the chairman and other people are now trying to do in the Senate and the House is to make sure that that kind of health care coverage the United States Senators have, which enables us to have the preventive health care and the best of treatment, is available to all citizens in this country. I believe we have to get to that point.

Senator STEVENS. You are right, Senator. I want to be quick to point out, though, that it is our health insurance that pays for the operations just like everyone else, and I think Senator Kennedy has raised the question of the lack of coverage of so many people in this country in terms of health insurance. There is a great gap out there in terms of health insurance coverage among those people who are really at risk in terms of prostate cancer. That has gotten my attention, and I would like to work with you in trying to close that gap.

Senator WELLSTONE. Thank you, Senator Stevens.

Thank you, Mr. Chairman.

The CHAIRMAN. About one in five Americans has an annual physical, less so in terms of men and higher in terms of women. So we've got a real challenge trying to do all the things we can in terms of preventive health care.

Senator, thank you very much for coming today. It is a very important message, and as an important member of the Appropriations Committee, we'll be talking to you about these matters.

Thank you very much.

On our second panel, it is a pleasure to welcome Ms. Zora Brown, director of the National Breast Cancer Resource Committee; Ms. Irma Goertzen, president and CEO of Magee Women's Hospital; Mr. Paul Berry, news anchor at Channel 7, an ABC affiliate in Washington, DC. We welcome as well Mrs. Berry, and we understand Tallie Berry is here as well, so we're glad to welcome the Berry family. And Dr. Harold Freeman, we're delighted to welcome you. Dr. Freeman has an international reputation as a cancer surgeon and is chair of the President's cancer panel. We are delighted to have all of you.

Ms. Brown, we look forward to hearing from you.

STATEMENTS OF ZORA K. BROWN, DIRECTOR, NATIONAL BREAST CANCER RESOURCE COMMITTEE, WASHINGTON, DC; IRMA E. GOERTZEN, PRESIDENT AND CEO, MAGEE WOMEN'S HOSPITAL, PITTSBURGH, PA; PAUL BERRY, NEWS ANCHOR, CHANNEL 7 (ABC) NEWS, WASHINGTON, DC; AND HAROLD FREEMAN, M.D., CHAIR, PRESIDENT'S CANCER PANEL AND DIRECTOR OF SURGERY, HARLEM HOSPITAL, NEW YORK, NY

Ms. Brown. Good morning. I would like to thank you, Senator Kennedy, and members of the subcommittee on health for the timeliness of this very important hearing on health promotion and disease prevention.

I am here today as a member of the National Cancer Advisory Board of the National Cancer Institute, a member of the DC Cancer Consortium, and as president of the Breast Cancer Resource Committee, but most importantly, as a survivor of breast cancer.

Breast cancer has riddled its way through four generations of my family. My great grandmother, grandmother, my mothers, and my three sisters and I were all treated for breast cancer, and aunts on both side of my family have been treated as well. My 18 nieces view themselves as time bombs. They do not ask the question as to whether I will get breast cancer, but when will I get breast cancer.

We know that in our case genetics obviously plays an important role. My family has waited, watched and listened while the new process of genetic manipulation for the treatment of breast cancer has been researched, discussed and debated, and we are hopeful that its application is as promising as it sounds.

We also know that prophylactic mastectomy is the only known preventive treatment for breast cancer. Prophylactic mastectomy is recommended at age 28 for women who have a family history like mine. One of my sisters was diagnosed with breast cancer at the age of 27 and had a bilateral mastectomy.

In spite of this tremendous family history, however, we do have a positive side. My family has an above-average education about this disease and its treatment options. We know that practicing breast self-examination is a must; that annual physical examinations are imperative; that having a mammogram is absolutely essential and that early detection and treatment is our best chance for surviving this disease.

When I was 22 years old, I had my first mammogram. The result of the mammogram detected dysplasia in a section of my right

breast. Approximately 10 years later, through breast self-examination, I discovered a pinhead-sized lump. I had already assembled a team of doctors who would treat me, obtained the best medical insurance coverage I could afford and prepared myself psychologically. As soon as I discovered the lump I was able to see my doctor and obtained treatment immediately.

I was given several treatment options, including chemotherapy, lumpectomy along with radiation and chemotherapy, or a modified radical mastectomy. Because of my family history and the information available to me more than 10 years ago, I chose to have a modified radical mastectomy.

In early 1989, one of my sisters who had been diagnosed and treated for breast cancer 12 years before had, for the third time, a recurrence. This time, her prognosis was grim. She died last December.

We both realized, though, at that time that something more needed to educate women about this disease, and it is as much because of my personal experiences as it is my sincere concern for the survival of women, particularly black women, that I am testifying here today. Black women have the highest mortality rate for breast cancer among women of all ethnic backgrounds.

With this in mind, it is imperative that information on the causes, incidence and treatment of breast cancer be disseminated nationally. Breast cancer respects neither age, economic status, or racial diversity.

The Breast Cancer Resource Committee was founded by me and my late sister, Belva Brissett. We established as our goal in 1989 the reduction of the mortality rate from breast cancer among black women. The primary audience for the efforts that we have initiated have been low-income black women in neighborhoods that are usually served last or minimally.

Questions concerning whether or not low-income women can be reached have been dispelled. Yes, they can be reached, they want to be reached, and they should be reached. And without a doubt, black women in the Washington, DC effort have benefited from the efforts of the Breast Cancer Resource Committee and from community hospitals like the Greater Southeast Health Care system and Howard University Hospital and from individuals like Dr. Alfred Goldson, chief of radiation oncology, and Dr. Robert DeWitty, chief of surgical oncology at Howard University, who have dedicated their time to free breast and cervical screening for low-income, uninsured women in the District of Columbia.

The number of outreach efforts has increased the number of black women receiving mammograms in DC, but unfortunately these efforts are still far from sufficient to stymie the epidemic that is plaguing the black community. While the survival rate for white women with breast cancer has increased, the survival rate for black women with breast cancer is steadily declining.

On September 28 of this year, the Breast Cancer Resource Committee invited 500 representatives of the major black women's service and social organizations to a symposium on breast cancer. We asked each organization to include as one of their many community outreach projects the education and dissemination of information on breast cancer to low-income black women in their commu-

nities. We asked them to join this fight from where they are—not form a new organization, but bring to bear the resources available to them to help save our lives.

At the time that this effort was initiated, I had no idea what an outpouring there would be for information, data and materials to support our program. Today I would like to take this opportunity to ask for your help in continuing our efforts to educate women about the benefits of screening mammography, surgical advances in breast cancer, the impact of drug therapy in prolonging disease-free survival, and the role nutrition can play in improving the quality of life.

While it remains urgent that women be exposed to the available information regardless of income, it is also important that we understand the cause and find a cure for breast cancer; that we seek ways to reduce the incidence of breast cancer; that we reduce the mortality rate of breast cancer, and that we ensure that women over the age of 40 are able to get a mammogram and that the mammograms are of the highest quality. When these challenges are met, the net impact on the health and survival rate of breast cancer victims among women of all races will be astronomical, and by extension, black women will benefit even more.

Even with these efforts, it is still of paramount importance that women are made aware of the strides and educated about the advances made in the search for a cure. And I would like to take a moment to applaud the National Institutes of Health for creating the Office of Research on Women's Cancer and appointing the very capable Dr. Vivian Pinn.

The Breast Cancer Resource Committee is committed to working unconditionally to ensure that black women, particularly low-income black women, receive the information and education required to make informed decisions concerning mammography, self-examination, early detection and treatment, and that access to treatment is available and affordable.

Again, I would like to applaud you for your efforts and thank you for convening this important hearing on health promotion and disease prevention.

Thank you.

The CHAIRMAN. That was very powerful testimony. Thank you very much. We share your enormous concern for those other members of your family and all women at risk in this Nation. It is a very revealing and distressing situation, and we admire your courage.

Ms. Goertzen, we are delighted to welcome you. We know other members of the family, Senator Simpson and I, and we are glad to have you here. Thank you very much.

Ms. GOERTZEN. Good morning, Senator Kennedy, Senator Wellstone.

My name is Irma Goertzen, and I am president and chief executive officer of Magee Women's Hospital in Pittsburgh, PA. I appreciate this opportunity to speak to you today about prevention and about the tragedy of breast cancer.

I speak to you today not only as an observer of women's health issues, but also as a participant. Magee Hospital for the past 80 years has focused solely on the health care needs of women and in-

fants, and as such, are quite concerned about the status of women's health in our country and the all too many health problems that women face—many for which we have no answers.

Today my focus, as I said is on breast cancer. I am going to share a couple of statistics with you and a few thoughts on how we can help women beat the odds that they will 1 day get this disease. First, however, I would like to share with you a story of a couple of women, the kinds of stories we encounter every day at Magee.

One of these women did not beat the odds against breast cancer; the other did.

Diane was all too familiar with the danger of breast cancer. It had killed her mother just 5 year ago at the age of 47. Knowing that this increased the likelihood of her getting breast cancer, Diane had diligently performed monthly self-examinations ever since.

Diane was just past her 30th birthday when 1 day, she was performing her regular routine self-exam and felt a lump in her breast. The first thing that came to mind was her mother. Her second thought turned to her doctor, who also felt the lump and referred her to a surgeon. The surgeon, however, quickly discounted the possibility of malignancy because of Diane's age and decided not to perform a biopsy. This left Diane hesitant, unsettled, she insisted upon a conclusive diagnosis. They did a sonogram found that this was also inconclusive.

She was told that the lump was probably a cyst and that it would go away in time. But the cyst did not go away, and after monitoring its progress for months, Diane returned to the surgeon, who finally removed the lump. The next day the pathologist's report arrived. Diane's lump was malignant. She had breast cancer just like her mother.

The doctor recommended a lumpectomy. She sought a second opinion and eventually underwent a segmental mastectomy, which is a procedure similar to a lumpectomy in which the lump, as well as a clear margin of healthy tissue, are removed in addition to the lymph nodes.

For Diane, the key to the procedure was the lymph nodes; if they were healthy, she was probably free of cancer. Diane was lucky. The lymph nodes were healthy. The surgery was over, the cancer scare gone, but now recovery had to begin. Diane completed six 3-week cycles of chemotherapy and six and a half weeks of radiation therapy.

Diane was lucky. After learning the hard way through the death of her own mother, she knew enough to understand that she suffered a high risk for breast cancer. She knew enough to perform self-examinations. She knew enough to be uneasy when her early fears were dismissed by her surgeon. Her survival today is a testament to her persistence, to her good sense and to the many miracles of modern medicine.

Judy, on the other hand, was not so lucky. Judy was 42 years old, with three children. She was a social worker who loved life. She was a fitness fanatic who rode her bicycle 15 miles a day; she didn't smoke, she didn't drink, and she had excellent eating habits. She had no reason to believe that she was at risk of developing breast cancer.

She was worried about a friend, though, so when that friend balked at the idea of going for a routine mammogram, Judy offered to go along with her just to keep her company and to have a mammogram herself.

Judy's mammogram was clear. She was healthy.

Three months later, however, Judy detected a lump in her breast while sitting in the bathtub. She returned to the doctor who, after a series of tests, determined that Judy was in the third stage of breast cancer—the final, most severe stage.

Judy underwent every form of treatment available to her—chemotherapy, radiation therapy. She suffered all of the symptoms—fear, pain, anxiety, anger, and helplessness. Most of all, she lamented that she would never get to see her grandchildren, including the children of her just-engaged son.

Sixteen months after Judy had gamely accompanied a friend to the doctor for a mammogram just to encourage the friend, Judy was dead. That was it. The mammogram wasn't enough to save her life. The radiation therapy wasn't enough to save her life, nor was the chemotherapy.

In the end, all we could do for Judy was give her the support to cope with what she knew to be her fate—and a wig to mask the effects of the treatment.

If I didn't know better, all this would make me sad. But I do know better, and instead of just making me sad, it also makes me kind of mad—mad because this scenario is replayed time and time again with thousands upon thousands of women a year; mad because too many women do not know what to do to check themselves for signs of breast cancer; mad because even when they do know, our own diagnostic tools are too often not good enough. And mad because even when we do have a reasonably prompt diagnosis, there are far too many cases when the treatment tools at our disposal simply do not do the job.

Yes, despite the development of new and better ways of diagnosing and treating breast cancer, this disease still affects far too many women. As you stated earlier, Senator, the American Cancer Society has predicted 175,900 women will develop breast cancer in the United States in 1991, and an estimated 45,000 women will die of the disease. Additional statistics show that one of every nine women will develop breast cancer during her lifetime. A few years ago, this number was one in 12, and it is predicted that by the year 2000, unless we do something, it is going to be one in 5. Start counting, ladies.

What can we do? How do we get to all of the women. Because the current best weapon against breast cancer is early detection, we at Magee have developed one of the largest breast care systems in the Nation. We have seven community centers located throughout the Pittsburgh area where 25,000 mammograms and 4,000 breast ultrasounds were performed last year. But that is only a small portion of the number of women in Pittsburgh getting mammograms. We did about 40 percent of the mammograms in our community, and if you just take number up, it's a very small portion of women who had mammograms.

We have also done a lot of counseling and education sessions. We feel that the success of the program in large part to date is due to

the fact that it is tailored to try to address some of the most common complaints that women have about breast cancer screening—inconvenience, fear, fear of radiation, and—a big one—discomfort.

But this is only a start. In an attempt to prevent the disease, we have set up a genetic counseling program for women who are at high risk of developing breast cancer because of family history or other associated risk factors. If an increased risk is identified for a particular woman, a tailored breast care program will be recommended for her.

As an affiliate hospital of the University of Pittsburgh, Magee is also a research facility, able to test and then, if warranted, quickly employ the most up-to-date technological advances. Currently, our physicians are conducting studies in stereotactic breast biopsy. This is a new nonsurgical technique that is performed on very, very small lesions identified only through mammography. Until recently, women whose mammograms detected small breast lesions had to undergo surgical biopsies. This new technique will allow physicians to perform a 40-minute procedure with only a local anesthetic. Approximately 100 women will be asked to participate in this study through December.

But with prevention and research, we have a very long way to go. Last Thursday my neighbor told me his daughter would be admitted to our hospital on Friday for "just a lumpectomy." But it didn't turn out to be so simple. The disease had spread throughout her lymph system and her lymph nodes, and in the parking lot last evening I talked to her physician, who said she has very bad disease. She is only 30 years old.

Breast disease, you see, is not a disease limited to a specific age, social class or ethnic group of women. It can happen to any woman—your wife, your mother, your sister, and yes, even our 30 year-old daughters.

Thank you very much.

[The prepared statement of Ms. Goertzen follows:]

Prepared Statement of Ms. Goertzen

Good morning. Senator Kennedy, members of the committee my name is Irma Goertsen and I am president and chief executive officer of Magee-Women's Hospital in Pittsburgh, PA. I appreciate the chance to speak to you today about the tragedy of breast cancer. Before I begin, I would like to take this opportunity to commend you for your leadership in the health care arena. Through the work of you and your committee a tremendous amount of good has been done for women's health and for that we are indebted.

I speak to you today not only as an observer of women's health issues, but also as a participant. Magee hospital—for the past 80 years has focused solely on the health care needs of women and infants, and as such, are quite concerned about the status of women's health in our country and the all-too many health problems women face—many for which we have no answers.

Today I will focus on breast cancer. I will share with you a couple of statistics and thoughts on how we can help women beat the odds that they will one day get this disease. But first, however, I would like to share with you the story of two women—the kinds of stories we encounter every day at Magee. One of these women beat the odds against breast cancer; the other did not.

Diane was all-too familiar with the danger of breast cancer. It had killed her mother just five years ago, at the age of 47. Knowing that this increased the likelihood of her getting breast cancer, Diane had diligently performed monthly self-examinations ever since.

Diane was just past her thirtieth birthday when one day, she was performing her regular, routine self-examination and felt a lump in her breast. The first thought that came to her mind was her mother.

Her second thought was to call her doctor, who also felt the lump and referred her to a surgeon. The surgeon, however, quickly discounted the possibility of a malignancy because of Diane's age and decided not to perform a biopsy. This left Diane hesitant, unsettled, and she insisted upon a conclusive diagnosis. A sonogram was performed, but even that test was inconclusive. She was told that the lump was probably a cyst, and that it would go away in time.

But the cyst did not go away, and after monitoring its progress for months, Diane returned to the surgeon, who finally removed the lump. The next day, the pathologist's report arrived. Diane's lump was malignant. She had breast cancer, just like her mother.

The doctor recommended a lumpectomy. She sought a second opinion and eventually underwent a segmental mastectomy, a procedure similar to a lumpectomy in which the lump and a clear margin of healthy tissue are removed, in addition to the lymph nodes.

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Judy, on the other hand, was not so lucky. Judy was 42 years old, with three children. She was a clinical social worker with a true love of life. A fitness fanatic who rode her bicycle fifteen miles a day, she didn't smoke, didn't drink, and had excellent eating habits. She had no reason to believe she was at-risk of developing breast cancer.

She was worried about a friend, though, so when that friend balked at the idea of going for a routine mammogram, Judy offered to go along with her, just to keep her company, and to have a mammogram herself.

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If I didn't know better, all this would make me is sad. But I do know better, and instead of making me just sad, it also makes me mad. Mad because this scenario is replayed time and time again, with thousands upon thousands of women a year. Mad because too many women do not know what to do to check themselves for signs of breast cancer. Mad because even when they do know, our own diagnostic tools are too often not good enough. And mad because even when we do have a reasonably prompt diagnosis, there are far too many cases when the treatment tools at our disposal simply do not do the job.

Yes, despite the development of new and better ways of diagnosing and treating breast cancer, this disease still affects far too many women.

The American Cancer Society has predicted 175,900 women will develop breast cancer in the United States in 1991, and an estimated 44,500 women will die of the disease this year. Additional statistics show one of every nine women will develop breast cancer during her lifetime. What can we do? How do we get to all the women?

Because the current best weapon against breast cancer is early detection, Magee has developed one of the largest breast care systems in the nation. In our seven community centers located throughout the Pittsburgh area, 25,000 mammograms

and 4,000 breast ultrasounds were performed last year. Countless counseling and education sessions were conducted in 1990. The success of the program is due, in large part, to the fact that it is tailored to address some of the most common complaints women have about breast cancer screening: Inconvenience, stigma, fear and discomfort. But this is only a start——

In an attempt to prevent this disease, we have set up a genetic counseling program for women who are at high-risk of developing breast cancer because of family history or other associated risk factors. If an increased risk is identified for a particular woman, a tailored breast care program will be recommended for her.

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Last Thursday, my neighbor told me his daughter would be admitted on Friday to Magee-Womens hospital for "just a lumpectomy"—but it didn't turn out to be so simple—the disease had spread throughout her lymph nodes—she is only 30 years old. Breast disease is not a disease limited to a specific age, social class, or ethnic group of women. It can happen to any woman. Your wife, your mother, your sister—and yes—even our 30 year old daughters.

Thank you for this opportunity and I would be happy to answer any questions.

The CHAIRMAN. Thank you very much.

Mr. Berry, we are glad to have you here. You are very good to come and speak to us about these issues, and we are grateful to you for your appearance.

Mr. BERRY. Thank you very much, Senator.

Good morning to you, Mr. Chairman, and to you, Senator Wellstone. I am thankful for the opportunity to address you this morning, and I applaud the time and effort being put forth on these all-important issues and topics of prevention and early detection.

My name is Paul Berry, and I live in the District. I am here with my wife Amy and our two children—our 3½ year-old son Talley, and our 2 year-old daughter Hudson. I am employed by WJLA TV, Channel 7, as a television news anchor and reporter. And while there is a very public side to our lives, we try to maintain a very private side, but in this instance feel it important, indeed a duty, to come forth with the experience of what was an all-encompassing and devastating part of our life.

We have survived an uninvited and unwanted dance with cancer. Because of that survival, we owe it to our God, to our families, to our friends, not to mention the wonderful doctors, nurses and medical staff at Georgetown University Hospital, who helped to make us whole again. And we owe it to our children, who were too young to understand then what was happening to us, but we owe it to them to do whatever we can to ensure that they inherit a world where cancer is a thing of the past.

I will leave all of the expert testimony to those far better able to explain the intricacies of these complicated matters, but offer to you this morning the simple details of what we lived through once it was determined that the life of my spouse was threatened by cancer. And, while I did not suffer the direct pain of being surgically cut, the intimate and real fear of dying, the anger of possibly leaving a spouse and children, and while I did not endure the scar-

ring, both physical and mental, and the intense personal and emotional trauma, I was nonetheless a victim of this terrible disease.

Our dance began back in August of 1989, the 18th of August to be precise, because my wife was on the delivery table undergoing a Cesarean section for the birth of our second child, Hudson. And while she endured the pain and strain of that procedure, holding my hand while the doctors struggled to bring Hudson into being, the anesthesiologist and I noticed that when she squeezed my hand, a lump would develop on the side of her neck. It was very pronounced, and he suggested that we should have it examined and looked at immediately.

Amy was unaware at the time, but following the delivery that morning, we were visited that afternoon by a surgical oncologist at the hospital. He examined Amy and suggested that something would have to be done immediately, by way of biopsy, but because of the C-section, further surgery would have to wait at least 2 or 3 weeks.

Less than 3 weeks later, September 5, Amy went in for the biopsy that turned into more serious surgery and the removal of the lump about the size of a plum from her neck. We were told to expect the best, that it could be benign, but warned about the worst, that it might be malignant. And sure enough, 5 days later, we learned that Amy was suffering from Dermatofibrosarcoma protuberans, a deadly form of cancer that, if it attacks the lymphatic system, could be deadly.

We were told that more surgery would be required, and 4 weeks later, October 4th, Amy was on the operating table again for what doctors described as a radical resection of the neck area and a skin graft. I was informed that it could not be determined if the surgery would remove all of the cancer cells, that very possibly it had already attacked the lymph nodes, and if true, her chances of survival would be less than 50 percent.

While I waited outside the operating room, all kinds of thoughts poured through my head: Why us? What did we do to deserve this? And I was saddened also with the realization that, until I found myself in this situation, I had no real idea of the impact of the real meaning of the word "cancer," the disease. Yes, I had lost my grandmother while fighting another form of cancer some 5 years before, but she was 86 years old then. Amy was just 34 years old at the time. So this had to be someone else's nightmare, not mine. But it was happening, and I waited and wondered whether I was going to lose my wife to this terrible disease.

The news that day was wonderful. They had caught the cancer in time, and Amy would survive, yes, she would, and then undergo every day for the next 3 months, radiation therapy, which destroyed her thyroid gland. At times, the treatment left her throat so sore that she could not swallow and could not eat. She still suffers the pain on her right side. But she would live, and we were thankful and very happy.

There were two other minor scares—growths in the arm and above her left sinus, toward the optic nerve. During the first part of 1990, she underwent surgery for both, and both were found to be benign.

We thought we were out of the woods and could get on with our lives. But that all came crashing down in August of 1990. It had been 1 year since the birth of our daughter when Amy went in for her one-year checkup. A routine pap smear came back with abnormal cells. While we held our collective breath, five suspicious areas of the cervix were biopsied, and the results came back positive.

She was diagnosed then with severe dysplasia, a form of cancer, and the need for more surgery, more anesthesia, and at the very least, a cone biopsy of the cervix, and at worst, at least for us, a full hysterectomy. The news was devastating. We were angry at the doctors, sometimes angry at each other, sometimes unable to share the pain and disappointment but, as we had done before, realized that we had each other, and we would make it, God willing. And willing he was. Amy once again cheated the disease of its painful victory. The doctors performed a cone biopsy, and a thorough check proved that the uterus was cancer-free.

Thanks to a timely pap smear, early detection in this instance most certainly saved her life. She is being watched closely by all of the doctors, and so far she remains cancer-free.

We are still thankful for the wonderful care that she received from all of the doctors and medical personnel that we encountered. There was no time to get ready, to learn how to handle the news that cancer was going to be a part of our lives. Fortunately, we had love and compassion for each other, and the love and support of our families and our friends.

But every step of the way was a learning experience, and we are keenly aware that we are blessed or lucky; that many people can sit here with far worse stories. But I think for all of us who meet this deadly disease head-on, we share some very common experiences.

The emotional and physical strain is enormous. Fortunately, I was well-known in a city that is well-known for its wealth of medical resources. Fortunately, I had the economic means to sustain the care that was needed. But even at our level this was devastating, and I shudder to think how those who are less fortunate can possibly handle the many different strains placed on the shoulders of the patient and his or her loved ones.

We learned early on that going head-first is the most important way—keeping the perspective that you can, that you will, that you must live, and that you will win. It is not easy, but it can be done, and it takes two people, fighting with everything they can, and sometimes fighting with each other, to win.

Obviously, we are fans of pap smears and early detection, and any legislation that will lend itself to making sure that those things happen. If it could save the life of my wife, it can help save some of the lives of those 5,000 to 7,000 women lost each year to cervical cancer in this country.

My lovely wife is present this morning, and each day I thank God for her, and I am able to suggest that early detection has also given us something else, something really wonderful. We are "in a family way," so to speak, as we learned last week that on July 4, 1992, if all goes well and it be God's will, our third child will arrive.

I sincerely thank you for this opportunity to tell my story, and I pray that it will help.

The CHAIRMAN. Thank you.

Dr. Freeman.

Dr. FREEMAN. Thank you for inviting me, Senator Kennedy.

I am very moved by the testimony that I have heard here this morning from Mr. Berry, Ms. Brown and the Senator, and I want to add a personal note myself.

I lost my father to cancer when I was 13 years old, and it was a very critical time. He was 45. He died of testicular cancer. If we had known then what we know now, that is, that approximately 85 percent of patients with testicular cancer are cured today, I think my father would have lived.

So we've made a lot of progress, Senator Kennedy. We declared a war against cancer 20 years ago, as you know, and in fact next month is the 20th anniversary of that very important act of President Nixon.

Declaring a war against cancer meant that we invested as a nation a significant amount of money into this research fight, and we have made extraordinary progress over the last 20 years. Particularly in the area of childhood cancer, we have raised the survival rate to the range of 80 percent, when 25 years ago it was in the range of 10 or 15 or 20 percent. This is remarkable progress.

As the testimony here has shown, from a Senator to a television broadcaster to a citizen, all of whom have experienced cancer in their families or themselves, cancer is a very liberal disease. I hesitate to use that word in the Senate because it means very different things to political people than I'm trying to say here today——

The CHAIRMAN. You are not offending anyone here. [Laughter.]

Dr. FREEMAN. Thank you, Senator.

By that, I mean cancer doesn't care who you are. It will strike the rich, the poor, the brilliant, the uneducated, the black, and the white. It doesn't have any conscience at all.

The problem, though, Senator, is that we are not as liberal as a society, in my opinion, in confronting cancer as the disease is itself in affecting people. So that there are segments of the American population who have a considerably more difficult time with this disease and other diseases.

For example, you've heard statistics today indicating that black women in particular have a lower 5-year survival rate when they develop cancer, as Ms. Brown has testified. Senator Stevens testified that black males will have the highest incidence of prostate cancer in the world. We don't know the reasons for that, and that is an area where much more research should be done.

By contrast, black males in Africa have been studied, and they have a very low incidence of prostate cancer. And in the 1940's, the rate of prostate cancer in American blacks was lower than it was in whites.

So as suggested by Senator Stevens, we are dealing with an environmental factor which we don't fully understand, and we need to do a lot more research in order to try to understand it.

I want to concentrate on the populations that have differing results. Senator, it is very difficult to separate a disease like cancer from the circumstances in which the disease occurs. The circum-

stances involve housing conditions, education, employment or lack of employment, lack of access to health care. You have been on the cutting edge of bringing some of these things out.

In the community where I work, for example, which is Harlem, 96 percent black, 41 percent poor, we have one of the highest death rates from cancer in America. In fact, in general, we showed in a study that a black male growing up in Harlem has less of a chance of reaching age 65 than a male growing up in the so-called Third World country, Bangladesh.

So if you are in New York City, you don't need to go a long way to get to the Third World. "If you are downtown, just take the A-train," as Duke Ellington said, and you'll get to Harlem, and that is a Third World community with respect to survival.

So I think it is very important today that we talk about these things and talk about access to health care as a primary issue. Access to preventive health care is an extremely important part of that. We have 37 million uninsured people in America, and we have 34 million poor American people—they are disproportionately minority people—but we're talking about a universal problem, not a racial problem per se. It affects some people more because there are more poor people among blacks, and that is something we have worked out rather well. The cause of increased death rate in black Americans is not because they are black. It is because they are poorer and less educated than others.

That should lead us to an attack on the problem. That should lead us to change our approach to the war against cancer at this watershed year, 20 years after it was declared. It is indeed more than a research war, Senator, as you know—and I'm not speaking against research; we need to increase research, we need to put more money to solve these basic problems—but it is really wrong to see that segments of our population suffer so disproportionately. So we need to not accept the point that we have 34 million uninsured American people who do not have access to even basic health care, less so to preventive health care. This has to be changed; this is not acceptable in America today.

In particular there are universal approaches that I think we need to think of very carefully, Senator. Universal access is basic, but when you get to specific communities where the death rates are higher, the simple provision of access is not a solution to these problems. One would have to look at geographically defined areas of increased death rate such as Harlem represents, such as areas of Appalachia represent, and think of creative programs that go across the bureaucracies that we tend to operate within.

We have to pay attention to a creative plan that is universally directed toward education, housing, employment and health care in one package to solve these very desperate problems that we find in such communities.

With respect to breast cancer in particular, I'm going to say a few words about that and then about prostate cancer. I have had 12 years of experience in screening for breast cancer in a poor community, which is Harlem. We have now screened 20,000 women in the community of Harlem—poor, black women, primarily—and in that group of women we have diagnosed 16 breast cancers per 1,000 new women. One-third of these women were in the early stage of

disease, and we can expect that most of them will be cured. By contrast, the women who came into Harlem Hospital, which is the hospital that serves the poor in that community, had only a 6 percent rate of Stage 1 disease.

So what I am suggesting, Senator, is that the provision of acceptable and accessible screening services to poor populations clearly will save lives. And I recommend that the bill that you are putting forth today, that has to do with screening for cancer of the breast and the prostate, be specifically directed toward areas of the population that are having the most difficult problems, and that relates to poverty and lack of education.

With respect to prostate cancer, as said before, Senator, we do not know why black males have such a high rate of prostate cancer. We do know that this is a very treatable disease when found in the localized stage, and as high as 85 percent of men are alive at 5 years with localized prostate cancer. But we have a population of men in the country of general, irrespective of rate, who do not avail themselves of the simple diagnostic techniques that are available like the digital rectal examination, the newer things on the horizon like prostate ultrasound and the prostate specific antigen which is being explored as a blood test which may diagnose this disease early.

I believe that the bill that you are putting forth with respect to the prostate is a very important one, and here again I think a combination of research to find out what is the proper combination of tests to use on the population, digital rectal along with ultrasound and prostate specific antigen, is something that we need to explore. We don't know all the research answers as to when these various tests should be done.

In summary, Senator, I would say that it is significant that this is the 20th anniversary of the war against cancer. I would suggest that we need to fight the war the same way we fought the war in the Persian Gulf when we finally won it on the ground. We need to fight a ground war on cancer along with the research war to translate the technology that we have gained through our research to all American people irrespective of their ability to pay. And what I suggest is that we declare a guerrilla war against cancer, hand to hand combat in all of the neighborhoods of American, to fight this disease.

Thank you very much.

[The prepared statement of Dr. Freeman follows:]

Prepared Statement of Dr. Freeman

prevention and detection of breast and prostate cancer

Prevention provides perhaps the most exciting opportunities for reducing the suffering from human cancers at this time in our history. We have learned the lessons from infectious diseases and heart disease that You can best reduce the morbidity and mortality of any disease by preventing it. However, like the therapeutic advances and the great basic research advances made in the last decades, prevention too, will be a slow and laborious process.

Breast Cancer

An estimated 175,000 American woman will develop breast cancer in 1991 and 45,000 will die,

Breast cancer accounts for almost one third of malignancies in women and the lifetime risk of the disease in American women is now one in nine. The mortality of breast cancer is rising (84/100,000 in 1980 to 112/100,000 in 1987). The relative five year survival rate for breast cancer is 75 percent. However, socioeconomically disadvantaged populations have significantly lower survival rates duo too late stage of disease on initial diagnosis and treatment. When breast cancer is detected in the localized stage a five (5) year survival rate of 90 percent can be achieved. Screening mammography starting at age 40 is recommended along with monthly breast self examination and physical exam by a physician. Access to screening, diagnosis and treatment must be made available, accessible, and acceptable to all American women if best survival results are to be achieved.

Most prevention strategies in cancer have come from epidemiologic studies which suggest relationships between exposures or lifestyle events and specific tumors. for example a woman's lifetime hormonal experience, measured as the early onset of menses and late menopause and the number of pregnancies, as well as other events such as obesity have been known for some to correlate with the incidence of breast cancer. There is also a strong familial pattern for this cancer. The incidence of this disease is extremely high in a woman who has a first degree relative who has experienced breast cancer. This is particularly true if the relative hid breast cancer at a younger than average age.

Basic research and animal studies have also demonstrated cause and effect relationships between hormonal factors and breast cancer. These findings have Led to studies using one or more hormonal antagonists as preventive agents in high risk women4 As these studies mature they will provide us data to design a variety of interventions in women to reduce the incidence of this disease.

Prostate Cancer

An estimated 122,000 American men will develop prostate cancer in 1991 and 32,000 will die. Prostate cancer is the second most common cancer and the second leading cause of cancer deaths in men. Approximately one out of eleven men will develop prostate cancer, Over 80 percent of all prostate cancers occur in men over the age of 65. The disease is more common in Western Europe and North America and is infrequent in Africa, Central America nod South America, Black American males have the highest incidence of prostate cancer in the world. Studies conducted internationally have shown that dietary fat may be a factor. The overall relative five year survival rate is 71 percent. For localized disease the five year survival rate is 85 percent.

For this tumor there is a major need for significant basic research to provide the leads on which prevention strategies could be implemented. At this time we have practically nothing to suggest effective strategies for prevention trials in humans. This can change if research in this relatively neglected area is stimulated by interest and funding support.

Prostate cancer presents quite a different picture form breast cancer. There are few Leads as to its risk factors. This tumor deserves a Tar greater recognition for its role in cancer deaths of older males and a greater effort in basic and epidemiologic research. While little except dietary fat has been uncovered that directly relates to the incidence of this tumor, its responsiveness to hormonal control might suggest some avenue of approach. At this point, to my knowledge, there are no basic or epidemiologic research studies that suggest strong leads for a prevention trial.

There are however, several exciting leads for early detection of this tumor. Since it is a relatively slow growing tumor early detection offers a significantly improved cure rate. The three modes currently being studied in humans are the prostate specific antigen, the time honored digital rectal exam, and various ultrasound approaches. Several studies are trying to determine the best combination of these methods for detecting the tumor in its earliest stages. While no one method appears to have the sensitivity and specificity that is desirable, perhaps by using them in combination we will arrive at a cost-effective means for detection. There are a number of basic studies looking for Serum factors, hormonal alterations and cytogenic markers that might be specific for the earliest changes of the prostate leading to the malignancy. Several research centers are looking at other radiographic methods and combinations of techniques to more accurately determine the foci of malignancy.

Not only will they do that, but of course, as is important in all human studies, they will also demonstrate for us the side effects and unpleasant potential complications of such therapy. Because we are talking about using preventive strategies in

otherwise healthy individuals, these factors are extremely important, since only minimal complications can be accepted in this group.

There are a number of leads and opportunities for better early detection strategies in this disease. As you know earlier detection is crucial to saving lives from breast cancer. For example, many investigators ire looking at genetic and other markers which will hopefully be predictors of a woman's risk for this disease. While there is not as yet a clear cut correlation as is seen has recently been found in colon cancer, the expectation for future research is to discover as abnormal or altered chromosomal segment that would provide an estimate of a woman's risk for developing a tumor. There are a number of exciting basic research studies which hold promise for developing leads for early detection of this disease. The significant incidence of familial occurrence of this disorder (i.e., mother, sisters, daughter) certainly suggests that somewhere in the genetic material there will be a genetic change which is essential for developing of this disorder. There are a number of promising studies looking at mucin proteins that are specific for breast cancer, which (if they are formed by breast cancer cells early in the disease) could lead to a test of blood or other body fluids that would herald the earlier stages of the disease leading to appropriate intervention and cure. Breast cancer specific antigens and their antibodies which can be radio-labeled and detected to provide yet another approach to screening for this disease.

There are new and exciting x-ray diagnostic tools in every stage of development from basic research to early clinical trials that will provide for improved accuracy and specificity of screening complementary to the mammogram. As important as these studies are, we must expand ways to encourage women to avail themselves of the known methods of diagnosis. There are clearly many socioeconomic and cultural barriers to medical care in this country and there are even higher hurdles regarding mammography, since it is still not covered by many of the insurance policies that are currently in effect. There are also a number of psychological barriers to screening—how do we motivate women to avail themselves of existing means for detection and take advantage of knowledge about other aspects of prevention as well? There are broad areas for research in this field which could lead to eventually understanding and breaking down these barriers and, the design of well defined interventions to overcome them.

The CHAIRMAN. Thank you very much, Dr. Freeman.

One of the more interesting health experiences and educational experiences that I've had in travelling overseas has been visiting the center in Grenoble where they do epidemiological studies on cancer around the world. I don't know whether you have had a chance to visit the center or are familiar with their studies. The results are enormously interesting. Specifically, the development of cancer from environmental factors. Approximately 85 percent of cancers are believed to be related to environmental factors. This is something that I think many of us believe, yet we the research efforts continue—and Lord only knows we are strong supporters of that, there remain so many increased opportunities now that aren't being pursued. This is frustrating but this is something that you may be familiar with. There may be new results from studies there. I will try to get up to speed myself on it, and it is something that you may want to get an update on yourself as we're talking about comparisons with Africa and the U.S., and Asia and the U.S. There has been an enormous amount of work on it.

We always emphasize and underline—and I know my good friend who has joined us, Senator Pell, does—about making sure we get the best of our information out into the world community as well as here, and I'm sure Senator Pell is going to ask you about that.

I am mindful as well in that access to health care, another issue I care very deeply about and I know Senator Pell does as well, is deficient.

I can remember when my son Teddy was being treated after being diagnosed with osteosarcoma in his leg, which, at that time,

had a poor prognosis and was predicted to be very, very dangerous, with a very limited chance of survival. He went through a newer regime that was going through experimentation at Children's Hospital. For a certain period of time, since it was experimental and was funded as a clinical trial by NIH, the families of the children who were involved in it did not have to pay for the cost for treatment. Well, about halfway through it, NIH said it was no longer experimental and was going to be recommended as a treatment. The treatment was $2,700, and you had to get it every 3 weeks for 2 years at that time—length of treatment is shorter now, and I can't tell you what the cost is at this particular time, but it would be very difficult for me to believe it has decreased, because very few of those kinds of drugs do go down.

But I can remember parents talking to each other outside the patient's room and wondering what the chance of survival would be for their child if they only had treatment for 10 months instead of 2 years, or eleven months, or fifteen months, and all of the anguish and the tears and the extraordinary anxiety which they had in trying to deal with this.

The Children's Hospital in Boston does a good deal to try to help relieve some of those financial pressures, but this is still a blight in terms of our society and one which we should be ashamed of.

I really have no questions. I see Mrs. Berry in the audience, and we want to thank you very much for coming. We also see that healthy little 3½ year-old. I ought to be able to identify children around that age. There were nine of us, 30 grandchildren, and there are 28 great-grandchildren, the oldest of whom is 10. So I can spot the difference between a two and a half and a 3 year-old pretty well—I can't always remember their names, though.

Senator Pell.

Senator PELL. I have just one question and that is to Dr. Freeman. You mentioned the chemical test that is given where you can identify prostate cancer when there is no other manifestation of it. What is that chemical test?

Dr. FREEMAN. There is a test, Senator Pell, which is called the prostate specific antigen which may identify prostate cancer as a blood test. It is being researched now to see whether it is reasonable to use this as a screening test, and my own guess is that it is not quite refined enough yet to apply it as a screening test, but we're moving in that direction, I believe.

Senator PELL. Thank you very much.

The CHAIRMAN. Senator Simon.

Senator SIMON. I regret I just got here. I am grateful for your calling the hearing, Mr. Chairman, and I shall read the testimony and look forward to the remainder of the hearing. I have no questions.

The CHAIRMAN. We thank you all very much for very moving and compelling testimony. Hopefully our legislation can help; I think it can.

Our third panel will focus on the neglected and often overlooked threats to the health of women and present information on the increasing threat to our children from inadequate immunizations. The human and economic costs for these conditions are both preventable and tremendous.

I'd like to welcome Dr. Pinn, who is the director of the NIH Office of Research on Women's Health; Ms. Helene Brown, the nationally recognized advocate for tobacco control and women's health; and Dr. Susan Lett, director of immunizations of the Massachusetts Department of Health.

Dr. Pinn has a national reputation in pathology and is former director of pathology at Howard University and provided tremendous leadership while president of the National Medical Association.

We are delighted to welcome the panel, and we'll start with Dr. Pinn.

STATEMENTS OF DR. VIVIAN PINN, DIRECTOR, NIH OFFICE OF RESEARCH ON WOMEN'S HEALTH, WASHINGTON, DC; HELENE BROWN, DIRECTOR, COMMUNITY APPLICATIONS OF RESEARCH, UCLA JONSSON COMPREHENSIVE CANCER CENTER, LOS ANGELES, CA; AND DR. SUSAN LETT, DIRECTOR OF IMMUNIZATIONS, MASSACHUSETTS DEPARTMENT OF HEALTH, BOSTON, MA

Dr. PINN. Thank you, Mr. Chairman, members of the committee.

I am delighted to be able to address you today, which is my second full day in the office as director of the Office for Research on Women's Health at the National Institutes of Health, and I think this is a wonderful way to begin my tenure in that office.

I am extremely excited about the challenges of this office and the opportunities that we shall have to improve the health and well-being of women of this country. Your support serves as a strong incentive to move forward with purpose and determination to achieve success in enriching the vitality and quality of life of women.

The world has changed in many ways since I was a medical student, at which time I was the only woman and only minority in my medical school class. Although women's health issues were not totally ignored, there were conditions that today are recognized and accepted as real entities that at that time were doubted as to their existence and certainly were not addressed in a scientific forum.

There has been a better recognition of the role of women in our society not just in the home and in child rearing, but also in the economic productivity of our Nation. This recognition has led to a difference in the perception of women's health issues. Women of today plead that their health issues not be viewed merely as those related to reproduction and contraception—but don't get me wrong; those are also important issues that do need further study and further definition—but they wish to also have their health issues include the vast spectrum of other conditions with significance at each stage of a woman's life.

Let me share with you some statistics. Deaths from cardiovascular disease, which in fact is the overall leading cause of death in all women, is too often understated and neglected. Two hundred and fifty thousand women die each year from myocardial infarction, and nearly half of all women who have heart attacks die within the first year as opposed to 31 percent of men.

In 1961, as you've already heard, one in 20 women developed breast cancer, while today we can expect one in nine women to de-

velop breast cancer. Approximately 20,000 women in the United States will be diagnosed with ovarian cancer this year. Osteoporosis affects nearly half of all women age 45 and as many as 95 percent of those over the age of 75. Osteoporosis leads to more than one million bone fractures every year. More than 90,000 women die each year from stroke, representing 61 percent of all fatalities from stroke.

We are witnessing a fundamental change sweeping our Nation regarding women's health today. Dr. Bernadine Healy, the director of NIH, has called it "an awakening." It has been said that women's health has finally come to the forefront of this Nation's consciousness.

Women's health issues are different from men's, and they do deserve special and urgent attention. They are critical not only for women but for the Nation as a whole. We will never confront satisfactorily problems such as the staggering rate of infant mortality in our country if we do not first improve the health of women. We cannot hope to improve the health of women without addressing other contributing factors such as behavior, poverty and access to health care.

Furthermore, provided that behavioral modifications do occur, and we do facilitate health care delivery, there must be simultaneously achievements in research to provide those answers so that we can give the answers and know what the correct preventive strategies should be and the correct therapeutic regimens should be once women, children or men do take advantage of the health care system. This, then, we see as the special contribution that NIH and hopefully through our office, we can and shall make.

Although women do tend to live longer than men, this does not mean that their longer life provides an optimum health status, nor does it mean that this longer life is ideal, for there are financial and societal costs associated with having a greater proportion of one's life spent elderly and typically, alone.

Women are both the primary recipients as well as the primary providers of long-term health care. Women have more chronic debilitating illnesses, seek more medical attention than men, take more medicines, and undergo more surgical procedures.

There is as well a disparity in the health status of America's women who are ethnic minorities or economically disadvantaged. We know that the rates for four of the five or six major causes of death in women are more than twice as high in minority women. We also know that for certain diseases in which the incidence rate may be less in minority women, we see higher mortality rates.

In the United States, 10 percent of AIDS cases are now women. But that number is climbing dramatically, and it disproportionately affects minority women. A large proportion of these women may in fact be i.v. drug abusers or have sexual partners who are i.v. drug abusers. But others are partners of hemophiliacs, have themselves had blood transfusions, may be partners of bisexual men, or are in the growing group of women whose only risk factor has been heterosexual contact.

Surely, the brave, smiling face of the beloved sports hero that we have seen in the press over the past 2 weeks will not just simply underscore the toll of heterosexual HIV transmission from the

viewpoint of our unsuspecting men, but will also focus on this same problem from the perspective of its toll on our unsuspecting women.

Indeed, social changes in our society have contributed to the health problems for women, especially young women. In addition to AIDS, these include other sexually transmitted diseases; cervical cancer, which we see affecting younger women, especially in relationship to the human papilloma virus; teenage pregnancy with embarrassing rates of infant mortality, and infertility. Substance and alcohol abuse, violence, cancer, homelessness are also among the major threats to our women.

Because much of the current knowledge is based on research in which the study populations were homogeneous, meaning they were predominantly men, one of our challenges in research is now to establish a science base that will permit reliable diagnoses, effective treatment, and preventive strategies for women—for as you know, while women today are not usually or not often included in clinical studies, women of childbearing age and pregnant women will have many of the same illnesses and diseases, and they must be treated for them. Yet, if we have not tested these medications and treatment modalities in such women, how do we know they will be effective, how do we know what their outcome will be on either the fetus or the women?

We must and shall pursue research efforts which can assist in filling gaps about women's health. We must and shall increase participation of women in clinical trials. And we will increase the participation of women in the conduct of such studies.

Our specific contribution to prevention will be through biomedical and clinical research to better understand, modify and deter the mortality and morbidity associated with conditions and diseases of women. Our challenge is to also assure that our scientific advances are available to provide inspiration and hope to the women of this Nation and of the world. And we also need to make sure that we address some of the specific health needs and concerns of this world and this country's disadvantaged women, including not just black and white women, but also Hispanic, Asian, Native American, women in rural areas, women in urban inner city areas, older women, the frail and the disabled.

Mr. Chairman, my task ahead is an enormous one, but I look forward to working with you and other members of the committee in order to make a difference in the quality of life of women of all ages and races and to make women's health a national reality.

I must commend you on the hearings today, and as you have already stated, in my previous career I was, and I guess I still am, basically a pathologist, and it has just been heartening to hear nonphysicians talk today about invasion of capsule, about prostate specific antigen, about malignant and benign, knowing words other than just what we basically in fact in the past would have been told were words not to use in polite company, because forums such as this and the opportunity to have the public as well as physicians learn more about what is going on cannot help but improve the status of health in this country for all Americans.

Thank you.

[The prepared statement of Dr. Pinn follows:]

Prepared Statement of Dr. Pinn

Mr. Chairman, and members of the committee, I want to thank you for the opportunity to address you this morning on my second day as director of the Office of Research on Women's Health of the National Institutes of Health. I am extremely excited about the challenges of this office and the opportunities, of which we shall take every advantage, to improve the health and well-being of this nation's women. That this committee has shown such commitment and concern about the health status of women serves as a strong incentive to move forward with purpose and determination to achieve success in enriching the vitality and quality of life of women.

The world has changed in many ways since I was a medical student, when I was the only woman and only minority in my class. Although women's health issues were not ignored, there were conditions that today are recognized and accepted as real entities that at that time were doubted as to their existence, much less addressed in a scientific forum.

The most profound changes have been related to the recognition of the role of women, of all women, in our society, not just in the home and in child rearing, but also in the economic productivity of our nation. This recognition has led to a difference in the perception of women's health issues as well as of the role of women in health initiatives from the biomedical, social, economic, cultural and, as this hearing exemplifies, political aspects.

Furthermore, women of today plead that their health issues not be viewed merely as those related to reproduction and contraception, which, themselves, are important and need further definition and understanding, but also the vast spectrum of conditions with significance at each stage of a woman's life span, from her birth to her older years, in addition to those related to her distinctive reproductive organs.

Let me share with you some statistics:

—Death from cardiovascular diseases, the overall leading cause of death in all women, is too often understated and neglected.
Two hundred and fifty thousand women die each year from myocardial infarction. Nearly half of all women who have heart attacks die within a year, as opposed to 31 percent of men. Nearly one in two female deaths in the U.S. each year is the result of cardiovascular diseases.

—In 1961, one in 20 women developed breast cancer. Today, as you know, one in nine women can expect to develop breast cancer.

—Approximately 20,000 women in the U.S. will be diagnosed with ovarian cancer this year.

—Osteoporosis affects nearly half of all women over 45, and as many as 90 of those over age 75. Osteoporosis leads to more than a million bone fractures every year.

—More than 90,000 women die each year from stroke, representing 61 percent of all fatalities from stroke.

We are witnessing a fundamental change sweeping our nation regarding women's health. Dr. Bernadine Realy, the director of NIH, has called it "an awakening." It has been said that women's health has finally come to the forefront of this nation's consciousness. This phenomenon is evident from the activity in Congress, the media, the research community itself, women's health advocacy groups, and from the tremendous number of women or their families across the country who have written to the NIH in the past year seeking advice, comfort and hope.

Women's health issues are different than men's, and they do deserve special and urgent attention. They are critical not only for women, but for the nation as a whole.

We will never satisfactorily confront problems such as the staggering rates of infant mortality in our country without improving the health of women, before, during and after their pregnancies. We cannot hope to improve the health of women without also addressing other confounding and contributing factors including behavior, poverty, literacy, and access to health care.

Further, provided that self-health behavioral modifications occur, and access to health care is facilitated, there must simultaneously be achievements in biomedical and clinical research to provide answers to the questions about health and disease in women which will be confronted. This, then, is the special contribution that the NIH can make. The ability of the health care delivery system to address such gaps in knowledge about women's health will affect not just our current generation, but generations to come.

Morbidity and mortality statistics for women reveal a dichotomy. Although women tend to live longer than men, this does not mean that their health status is optimum, nor their quality of life ideal.

And, there are financial and societal costs associated with having a greater proportion of one's life spent elderly and, typically, alone. Women are both the primary recipients and providers of long term care. Approximately 75 percent of nursing home residents are women. Women have more chronic, debilitating illnesses, seek medical attention more often than men, take more medicines, especially anti depressants and tranquilizers, and undergo more surgical procedures.

There is, as well, a disparity in the health status of America's women who are ethnic minorities or economically disadvantaged. For all women in the United States, as of 1990 the six leading causes of death were the following: Cancer (including lung, breast, and colon cancer), heart disease, accidents, homicide, cerebrovascular diseases, suicide, and AIDS. Five of the six loading causes or death—cancer, heart diseases, accidents, homicide, and cerebrovascular diseases—are the same for both white and African Americans. However, the rates for four of the major causes of death are more than twice as high for African American women than white women. These are cardiovascular and cerebrovascular diseases, homicide, and AIDS. And, there are higher mortality rates for certain diseases in minority women even if the incidence rate is less.

The relationship between the status of women—their roles in family and society—and their risk of disease has been demonstrated, in devastating fashion, by the epidemic of HIV infection.

In the U.S., 10 percent of AIDS cases are now women, but that number is climbing dramatically, and it disproportionately affects minority women. A large proportion of these women use intravenous drugs or are the sexual partners of IV drug users. Others are partners of hemophiliacs, recipients of blood transfusion, partners of bisexual men, or ore in the growing group of women whose only risk factor has been heterosexual contact.

The World Health Organization has estimated that by the year 2000, the proportion off men and women worldwide who are HIV infected will be nearly equal. Surely the brave, smiling face of a beloved sports hero in the press over the past two weeks will not just underscore the toll of heterosexual HIV transmission from the viewpoint of unsuspecting men, but will also focus on this same problem from the perspective of its toll on our unsuspecting women.

Indeed, social changes in our society in the past twenty or thirty years have contributed to the health problems for women, especially young women. In addition to AIDS, these include other sexually transmitted diseases, cervical cancer in younger women related to the human papilloma virus, teenage pregnancy with embarrassing rates of infant mortality, and infertility. Substance and alcohol abuse, domestic violence, lung, breast, ovarian, and colon cancer, and the overwhelming problems of homelessness are also among the major health threats to our women.

We need to better understand the interrelationship between society's emphasis on women's physical attractiveness and girls' concerns about their bodies, and the development of eating disorders, obesity, depression, and suicide.

Biomedical research alone cannot correct the disparities, inequities, or insensitivities women face in the health care system, but we do have a critical contribution to make. Because much of our current knowledge is based on research in which the study populations were predominantly men, the challenge now facing the NIH is to establish the science base that will permit reliable diagnoses, and effective treatment and prevention strategies for women.

It is the role of the NIH to identify and investigate the gaps in knowledge about diseases and conditions that affect women. We must and shall pursue research efforts, including basic science, clinical investigation and clinical trials, which can assist in filling these gaps and lead to appropriate clinical interventions and applications. We must and shall increase the participation of women in clinical trials. And we will increase the participation of women in the conduct of such studies.

To ensure that these activities are addressed throughout the NIH, the Office of Research on Women's Health (ORWH) was established within the office of the director of NIH just one year ago. The mandate of this new office is to strengthen and enhance research related to diseases and conditions that affect women.

Within this overall mandate, the office has three critical objectives. The first is to ensure that all research conducted and supported by the NIH adequately addresses the important issues of women's health. These issues have been defined broadly as diseases, disorders, and conditions that are unique to, more prevalent among, more serious in women, or for which there ore different risk factors or interventions for women.

Our second objective is to ensure appropriate participation of women in clinical research, especially in clinical trials. The well-publicized instances of women's exclusion from studies of cardiovascular disease, for instance, served as a lightening rod to bring about important changes in the way trials will be conducted henceforth.

The third key objective is to direct efforts toward increasing the number of women conducting this research—that is, women as scientists and researchers.

A guiding principle of all our efforts is the conviction that biomedical research must be targeted to all of America's women, of all races, ages, and socioeconomic and ethnic groups. We recognize as well that women's health needs are tied inextricably to other critical social and economic issues, and that our efforts must address both biomedical and behavioral issues, the body as well as the mind.

To address the first objective, increasing the level of attention given to women's health research, the ORWH has pursued a year-long process to help define an NIH research agenda for women's health for the coming decade. To that end, advice was sought not only from the scientists and experts within and supported by the NIH, but also from women's organizations, advocacy groups, and consumer organizations who provided testimony at a public meeting in June. On September 4–6, ORWH held a meeting which was the culmination of this process—a scientific workshop of women's health research experts from across the United States. This meeting focused not only on the scientific issues affecting women's health, but looked at these issues across a woman's life span, from birth to the later years. Ten working groups are now in the process of drafting and reviewing the report and making final recommendations based on the discussions at this very important meeting, attended by more than 275 people. We anticipate that the report of this exciting meeting will be complete by early next year.

The second objective, ensuring participation of women in study populations, has been one of the highest priorities this year. The office responded to each of the criticisms and recommendations of a GAO report requested by Congress, and has implemented a strengthened and revitalized policy on the inclusion of women and minorities in study populations.

The policy clearly states that: (1) adequate numbers of women shall be included in clinical studies proportional to prevalence of the condition under study; (2) any justification for not including women in such studies will be evaluated by the peer review group assessing the proposal and, if not considered to be appropriate, will be factored into the final recommendation for approval or disapproval of the proposal; and (3) the NIH/ADAMHA funding components will not fund/award grants or contracts until the applicant provides sufficient information on the study population to assure compliance with NIH/ADAMHA policy on inclusion of women in study populations.

The concluding sentence in the *NIH Guide for Grants and Contracts* announcement states that, "regardless of the program relevance of the proposed research, the NIH will not fund/award grants or contracts that do not comply with this policy." The policy applies to the NIH intramural program as well. Grant and contract applications are coded, and the office is in the process of establishing a system to track and monitor the inclusion of women and minorities in studies.

But what are the implications of this policy? Why have women been historically excluded from research? Was their exclusion an act of discrimination or of protection? Women were excluded for many reasons. Some of the stated reasons included that cyclical hormonal changes confound results; the study population would be less homogeneous; study costs are higher if gender-specific hypotheses or sub-group analyses are anticipated; recruitment to studies of women is more difficult—many have transportation or day care needs to be considered; and there are legal and ethical issues surrounding potential exposure to a fetus.

Many treatments and modalities will be used in pregnant women or women with childbearing potential, for instance, but if they have not been tested in similar women, we do not know the potential ramifications on the fetus or fertility of such women. These issues may be obstacles, but not insurmountable ones. In order to resolve these complex issues, our office is working with the Institute of Medicine to address the medical, legal and ethical implications of including women in clinical trials.

We will assess questions such as:

—Is it possible to include women of childbearing age in clinical research while dealing with problems related to potential fetal damage, safety, and liability?
—What guidelines should be developed to determine under what circumstances changes in drug metabolism (and even surgery) should be investigated in relation to phases of the menstrual cycle?

—Can guidelines be established to determine when clinical studies should be designed to evaluate gender difference?

With the limited funds available in FY 1991 ($816,000), the ORWH recently funded its first awards, providing supplemental funds to existing research grants, supported by the various institutes, to scientific investigators across the country. These funds are to expand high-priority research related to women's health and to specifically increase the number of women, including minority women, in such studies. Twenty supplemental grants were awarded—a 50 percent award rate. We are especially pleased that one-half of the Principal Investigators of these grants happen to be women.

The supplements support basic biomedical studies, large community health projects, and research in clinical areas including breast cancer, heart disease, AIDS, sexually transmitted diseases, arthritis, interstitial cystitis, hearing loss, dental disease, incontinence, and a number of issues related to aging.

In funding research in this manner, our off ice can be a catalyst and a facilitator, sharing responsibility with the Institutes, Centers, and Divisions and supporting and augmenting their efforts.

It is our firm belief that research on women's health should not be segregated from the rest of the research enterprise in a separate women's health center if issues of women's health research are to truly become a universal concern and priority rather than an endeavor of a few.

Recognizing that part of the problem in including women in clinical trials is the Institutional Review Board process, we are planning a meeting of chairs and administrators of IRB's in the near future, in order to utilize the combined expertise in finding ways we can overcome some of the barriers investigators must face in their own institutions.

Our third goal, nurturing women not only as scientists, but as leaders in research, will be a top priority for our efforts in the coming year. The office will host a conference in 1992 focusing on how we can attract, promote and maintain women in scientific careers.

However, we cannot depend on solutions occurring simply by increasing the number of female scientists, researchers and physicians. We must train and sensitize all health professionals to understand not only the medical needs of women, but to take the time to listen to their patients, to respect their concerns and anxieties, and, most of all, as so many women have consistently told us, to take them seriously.

Finally, I'd like to tell you about a new initiative, about which you have already heard Dr. Healy speak. It is the most definitive, far-reaching study of women's health ever undertaken. The Women's Health Initiative, over at least a 10 year period, will examine heart disease and stroke, cancer (particularly breast cancer), and osteoporosis—the major causes of death, disability and frailty in postmenopausal women of all races and socioeconomic strata. These are all important priorities for women's health, and were among the top recommendations of the Workshop on Research opportunities for Women's Health.

The Initiative has three components: A large prospective surveillance study, a nationally-based community intervention and prevention study, and a series of randomized clinical trials. The study will examine the effects of menopause on disease in older women, as well as those of diet modification (specifically a low-fat diet and dietary supplements), smoking cessation, use of hormone replacement, and physical exercise.

Due to the size and importance of this study, we recently held a 2-day meeting to give the scientific and lay communities an opportunity to provide suggestions and comments before the protocol is finalized. At that time, the study's Scientific and Technical working Group presented the proposed study design and parameters to the public, including women's organizations, professional societies, and the press.

Participants were invited to provide testimony regarding their concerns and recommendations about the study design and philosophy. We believe this was another important step in including women not only as study subjects, but as participants in the decision-making process about research concerning them.

We believe that this study will also afford us the opportunity to learn more about recruiting and maintaining female participants in trials, an important piece of information which we will be able to apply to many other studies.

As such, this study is one of the major elements of the NIH long-term plan for women's health research. But it is by no means the only element. You can expect that further studies and initiatives, addressing important issues for women across all the stages of their life span, will be forthcoming.

Our future initiatives will be guided by the report and recommendations of the Workshop on opportunities for Research on Women's Health, in concert with the NIH Strategic Plan, which includes a series of initiatives regarding the health of minorities, women, and the underserved. With the additional funds provided by Congress, we hope to fund or co-fund other priority research areas and initiate other trans-NIH studies related to women's health.

Our office participates in the Public Health service coordinating Committee on Women's Health, which is co-chaired by Dr. James Mason and Dr. Ruth Kirschstein, who preceded me as acting director of the ORWH. This group has presented to Congress a PHS Action Plan on women's health, which brings together all of the important players throughout PHS who must work in concert to provide not only research, but services, education and prevention activities that are accessible and relevant to women. An Office on Women's Health has recently been established within the office of the Assistant Secretary for Health to oversee implementation of this Action Plan.

We are committed to working to increase recognition of the importance of health problems specific to women such that adequate and appropriate research and its clinical application can result in an improvement in the current status of women's health and the quality of their existence into advanced age.

Our specific contribution to prevention is through biomedical and clinical research to better understand, modify and deter the mortality and morbidity associated with conditions and diseases of women. Our challenge is to also assure that our scientific advances are available to provide inspiration and hope to the women of this nation and of the world.

Mr. Chairman, my task ahead is an enormous one, but I look forward to working with you and other members of the committee in order to make a difference in the quality of life of women of all ages and races, and to make women's health a national reality.

This concludes my prepared statement. I would be pleased to answer any questions you may have.

The CHAIRMAN. Thank you very much. That is very encouraging.

Ms. Brown.

Ms. BROWN. Senator Kennedy, Senator Pell, Senator Simon, I am pleased to be here today and to represent a portion of the women of the Nation who are concerned about the use of tobacco.

Thanks for Senate Bill 1944. This is the kind of bill that represents our best hope. We know with every fiber of our being the worth of our lives, and we are desperately seeking the opportunity to live them to the fullest without being lured into use of a nondeclared drug called tobacco, to find out only some years later that we invested in our own illness and in our own death.

We acknowledge the fact that a considerable investment is made daily in smoking directed at women. It is in the billions, and it is all from the tobacco industry. Adding insult to injury, their ads are aimed at the most vulnerable of our citizens, mainly those with a decided emphasis on women who are in the age range of 24 to 60. They are the working uninsured. They are the women in the WIC program. They are the women in childbearing years, and they are the young women who mistake a Kool for "being cool."

Over 400,000 people are going to die this year of tobacco-related diseases. Today we've come a long way in what we have already done with information dissemination, with education. We have convinced 38 million people to quit smoking—but the bad part of it is that 50 million are still smoking. And teenage girls seem to pick it up sooner, faster, and inhale deeper than any of the others in our society.

More than 3,000 teenagers will become regular smokers by the end of today. In 1987, for example, more women died of lung cancer

than died of breast cancer for the first time in the 40 years that we have been keeping those statistics.

We have the perfect example here this morning of the complexity of a disease. We talked about breast cancer, for which we have no real preventive method, but we can detect it early enough to cure it. Now we're talking about something like lung cancer, where we have no way of detecting it early enough to cure it. Our cure rate when detected is close to zip, maybe 12 to 15 percent. But we can prevent totally those lung cancers that are caused by cigarette smoking.

For women, this is a special disaster, and they are the casualties. They are the victims of a network of social and political factors which encourage the growth of tobacco, the bombardment of slick advertising, and the use of tobacco as if it were a worthy additive to fruitful living, while knowing every step of the way that it is the single most preventable cause of death in our society. It is indeed now a women's issue.

When the man in the family dies, for many families, the total family income ceases to be, and the wife and the mother struggles with trying to make a living, to be both parents to her children, and her life from day to day becomes a system out of control.

It is even more disastrous when the mother is ill and then dies. The family income then is usually cut in half and half again to pay for child care and homemaker services. Emotionally, there is no filling the void. The nurturing care of a mother is nothing that you can buy in the open market. And because tobacco is well-known as a gateway drug, the use of other drugs by children takes its place in line, and then they drop out of school, and instead of becoming productive members of society, we find that the loss of the mother has cost us the lives of the children as well.

We all know that dying is a very easy thing; there is no trick to it. Living is what is difficult. There is not a single tobacco-related disease that kills you fast. The guillotine does that. Four thousand people this year will die due to smoking-related deaths, and none of them will die easily or quickly. They will live in a most disabled fashion. They can't talk because they have had strokes. They can't walk because they have had strokes. They can't breath without carrying portable oxygen with them because of emphysema.

Dr. Pinn has listed for you the killing, death-defying diseases today, and almost all of them, as I listened to her go down the list, are directly related to cigarette smoking in one way, shape or form. Osteoporosis, kidney cancer, bladder cancers, mouth cancers, esophageal cancers, tongue cancer, infertility, infant mortality—everything that she named and that I can scoot out of my mouth are almost directly related to cigarette smoking.

I don't have to inventory for you the costs of these illnesses. Your committee and you have addressed health access in this country before and in another setting. But how foolhardy it is for us to continue to treat and not to try to prevent.

I don't come here today seeking the funding for another new hospital or more physician training or another new biomedical discovery or another nurse or another bed or another drug. That's not what we're talking about. We have developed the skills, and we have the ability to put to work on a person-to-person level all that

we know already about how to get people to quit and how to keep teenagers from starting.

Thanks to you, Senator Kennedy, this bill addresses a good portion of those needs. Make no mistake—every, single neighborhood has talent in it in this country. Through training and national demonstration projects, every woman can become an educator—every woman. For this, we all speak the language that we need. Their influence can bring the message forcefully to others. They will be the advocates who will bring about the social norm of not smoking. They will influence their children. They will influence the schools. They will demand that tobacco, a well-documented drug, be regulated as a drug. They will disseminate information from person to person, and they will, as teachers, as aides, as mothers, as well-trained voices, see that curriculums that have already been developed find their way to the ears of the children.

Lest you think it cannot be done, let me remind you of the polio inoculation system that involved every school in the Nation. Parents recruited every family's participation by educating themselves in how to recruit, what to say, how to develop the materials, how to work with the program, how to work with the system, and how to reduce mortality for our children.

Lest you think it cannot be done, let me remind you of what took place in California less than 2 years ago. We passed the bill bouncing a cigarette tax of 25 cents per package to support anti-smoking activities. And in the first 2 years, smoking decreased by 14 percent. It was a people's initiative. People, by the ones, contributed over $1 million to fight the $22 million that the tobacco industry put up against that initiative.

When you get people by the ones talking to each other, they know what the answer is going to be. Was it easy? Was it cheap? Was it simple? Not on your life. However, we learned an important lesson then, and we are about to learn it again. We could accomplish more today, through education and information dissemination relative to tobacco than we can in any other way. But it takes a bill like this; it costs money, time, effort and energy. And if we as a nation are unwilling to pay those costs, then I think we are going to forever pay a high price of ignorance.

The women in this country are not ignorant, and they don't want to pay the cost for not knowing, nor do they want their children to. Health promotion, disease prevention—it's time has come.

I thank you from the bottom of my heart for what you've done in putting this bill forward, and I can guarantee you that we can do something very important with it.

Thank you.

[The prepared statement of Ms. Brown follows:]

Prepared Statement of Ms. Brown

Mr. Kennedy, honorable committee members and staff, members and guests. Representing the women of the nation at this hearing is a most pleasurable occasion for me. We know with every fiber of our being the worth of our lives and we desperately seek the opportunity to live them to the fullest without being lured into using a non declared drug only to find that some years later we invested in our own illness and death.

We acknowledge the fact that a considerable investment is made daily in smoking directed at women. It is in the billions and all from the tobacco industry. Adding

insult to injury their ads are aimed at the most vulnerable of our citizens . . . mainly those, with a decided emphasis on women, who are in the age range of 24–60. They are the working un-insured, the WIC (Women, Infants and Children program) mothers, those in child bearing years and the young who mistake a Kool for being cool.

Over 400,000 people will die this year due to tobacco related diseases. There are today about 38 million ex-smokers but 50 million who are smokers. Smoking rates are higher among blacks, blue collar workers and less educated people. Children, especially girls, are starting to smoke at earlier ages. More than 3,000 teenagers become regular smokers each day in the United States. In 1987, for the first time, more women died of lung cancer than died of breast cancer which for over forty years was the major cause of cancer death in women.

For women, a special disaster is looming. They are the casualties. They are the victims of a network of social and political factors which encourages the growth, the bombardment of slick advertising and the use of tobacco as if it were a worthy additive to fruitful living while knowing every step of the way that it is the single preventable cause of death in our society.

Smoking is indeed now a women's issue. When the man in the family dies, for many, the total family income ceases to be and the wife and mother struggles with trying to make a living and to be both parents to her children. Living from day to day becomes a system out of control. It is even more disastrous when the mother is ill and then dies. The family income is cut in half and then half or more again to pay for homemaker or child care costs. There is no substitute for the nurturing care of a mother and children become more used to living in the streets than they do at home. The emotional hole is never filled and the void is eased by smoking and use of alcohol. Then, because tobacco is well known to be classified a "gateway drug," use of other drugs, dropping out and instead of becoming a productive member of society we find that one woman's life has cost us the lives of the young as well.

We all know that dying is easy . . . it is living that is enormously difficult. There is not a single tobacco related disease that kills quickly . . . like the guillotine. While 400,000 die this year for many, they lived, and a new group is living, those final years unable to walk, to talk or to move their arms. Stroke robbed them of control of even their most intimate habits and heart disease and emphysema made even breathing a labored affair. The fearsome duo of tobacco and women brings osteoporosous, cancers of the lung, bladder, kidneys, mouth, esophagus, larynx, tongue and neck, infertility, early menopause and is a direct cause of death of 4,000 infants yearly.

You know far better than I the enormous costs of the illnesses and therapies. I will not inventory or detail those to you. Because there is no manner in which most of these can be detected early enough to effect cure it is now time to move to the preventive mode . . . how foolhardy we would be to continue to treat and not prevent.

We do not need or seek funding for another hospital, or more physician training or another new biomedical discovery or another nurse or bed or drug. We have developed the skills and have the ability to put to work at the person to person level all that we know about how people quit using tobacco and how youngsters can be convinced not to start. Thanks to you, Senator Kennedy and your committee, S. 1944 addresses many of these needs.

Make no mistake there is talent in every neighborhood in this country. Through training and national demonstration projects every woman can become an educator. For this we all speak the language needed. Their influence can bring the message forcefully to others. They will be the advocates who will bring about the social norm of not smoking. They will influence their children and the schools. They will demand that tobacco, a well documented drug, be regulated as a drug. They will disseminate information from person to person and they will, as teachers, aides, mothers and well trained voices see that the curriculums already developed and offered to the schools are used, understood and accepted as each child strives to accept personal responsibility for his or her life and well being.

As true as it is that tobacco money is funding women's organizations all over the country with the hidden agenda of keeping them quiet I do not, for a moment, think they'll be successful. They've underestimated the size of the brain in the female head.

Least you think that it cannot be done I remind you of the polio inoculation system that involved every school in the nation. Parents recruited each family's participation by educating themselves in how to recruit, what to say, how to develop the materials, how to work the program, how to work the systems and how to reduce mortality of our most precious assets . . . our children.

Least you think it cannot be done please allow me to tell you that in California where a cigarette tax of 25 cents per package was levied to support anti-smoking activities the price of cigarettes has declined 14 percent.

This was a people's initiative and people by-the-ones contributed over $1 million to see that the ballot measure succeeded. The tobacco industry spent more than $20 million peddling their messages of death, aimed in no small way directly at women, in opposition. They lost BIG . . . as the voice of the people came through loud and clear.

Was it easy? Was it cheap? Was it simple? . . . not on your life. However, we learned an important lesson then and we're about to learn it again . . . we can accomplish more through education and information dissemination about the impositions of tobacco than we can in any other way. But it is expensive in time, effort, energy and money. However, we must be willing to pay those costs. If we are unwilling to pay those costs then we will forever pay the enormously high price of ignorance. I, for one, will not be party to paying that bill so I am here begging you to lead the bombardment of our nation in the cause of health promotion, not destruction, from the weed called tobacco.

Again, my thanks for allowing me this time to speak with you today.

The CHAIRMAN. Thank you very much.

Dr. Lett, we're delighted to welcome you.

Dr. LETT. Good morning, Mr. Chairman and Senator Simon. My name is Dr. Susan Lett, and I am the medical director of the immunization program at the Massachusetts Department of Public Health.

I'd like to commend this committee for your support of the Preventive Health and Preventive Services Block Grants and the National Childhood Vaccine Program and for your interest in immunizations.

I appreciate the opportunity to come here today to talk to you about these issues. In my testimony, I will review the significance of vaccine preventable diseases prior to the availability of immunizations. I will tell you of the tragedies that occur when we fail to immunize our children, and I will tell you of the deaths and disabilities they suffer.

I will tell you how funds from the block grant and the national vaccine program led to a decrease in cases and deaths from these diseases over the past 20 years. But I will also describe how these diseases have recently returned to certain parts of this country where children are not adequately immunized. I will then describe certain aspects of the Massachusetts immunization program that might interest the committee.

The past four decades have been years of phenomenal progress in all areas of medicine. Yet in terms of lives spared or productive years spared, nothing rivals preventive pediatrics, specifically immunizations.

Immunizations have long been the cornerstone of preventive health care, and few other health services, whether curative or preventive, have proven to be so cost-effective. The benefit-to-cost ratio of some of the major childhood vaccines are outlined in Attachment 1 of my testimony. These ratios are based on acute medical costs only and do not include such indirect costs as loss of income. Yet by comparing the cost of vaccine to the expense of treating diseases they prevent, you can clearly see the value of immunizations.

I'd like to just review some historical background now. Most people can remember when, in the pre-vaccine era in the United States, 15–20,000 cases of paralytic polio occurred each year. Most people can remember how tetanus or "lock jaw" sometimes oc-

curred in adults after puncture wounds. However, most people don't remember that babies died of tetanus in this country because of infected umbilical cords; that there were between 500,000 to 4 million cases of measles each year, with between 1,000 and 3,000 deaths; that there were between 300,000 and 500,000 cases of pertussis or whooping cough each year, and that in some years between 10,000 and 30,000 people died in the United States from whooping cough.

The health complications caused by the vaccine preventable diseases can be extensive, and they include inflammation of the lungs, heart, brain and other organs, often resulting in permanent damage. Victims can suffer from seizures, permanent neurologic damage including paralysis and deafness, blindness and sterility. Birth defects and mental retardation also occur.

The care of children with these disabilities places great demands on our public hospitals, schools and rehabilitation programs. For this group, the number of years of productive life lost is enormous, and the emotional impact on their families and themselves is immeasurable.

Vaccines against pertussis, diphtheria and tetanus became widely available in the 1950's, and polio vaccine was first released in 1955. During the 1960's and early 1970's, vaccines against measles, rubella and mumps were licensed. At this time, the National Childhood Vaccine Program was created by the Federal Government and administered through the Centers for Disease Control. This program provided funds to States to ensure the adequate immunization of their children. Additional resources for State programs were made available through the Preventive Health and Health Services Block Grants.

In 1977, a series of national initiatives to reduce cases of vaccine preventable diseases were implemented. The initiatives consisted of aggressive disease surveillance and control measures and the enactment and enforcement of school immunization laws.

By 1980 in the United States, we saw a 98 percent reduction in vaccine preventable diseases. But during the 1980's, cases of these diseases began to rise again, and the vaccine preventable diseases that occurred in 1990 are outlined in Attachment 2.

Attachment 3 shows that in 1990 almost 28,000 people contracted measles, and of those 90 people died. More than half of those deaths occurred among children younger than five, and although the number of cases in 1990 is only 3 percent of those cases reported at the time of peak incidence, this is the largest number of cases that have occurred in a single year since 1977 and the largest number of deaths since 1971.

Failure to vaccine children at the appropriate age was the major factor contributing to this resurgence of measles in this country. In areas where outbreaks occurred, surveys showed that as few as 50 percent of the children had been vaccinated by the time they were two. There were many complex factors contributing to the low vaccination rate. People faced such barriers as inconvenient clinic hours and locations and lack of walk-in services. Non-English-speaking patients were unable to communicate with clinic staff. Also, there were missed opportunities when clinic staff failed to use every health encounter as an opportunity to vaccine or failed to

use multiple vaccines. In some cases, lack of vaccine and adequate personnel to staff clinics was also a problem.

Many of these factors were exacerbated when public clinics became overburdened by patients who could once afford private sector care. The increase in patients switching from private to public health care will continue with the current recession.

A national resurgence in rubella and congenital rubella syndrome has also been reported. Congenital rubella syndrome occurs in children whose mothers acquire rubella during pregnancy. The defects associated with it include mental retardation, severe cardiac and eye problems, deafness, bone deformities and growth retardation. In 1990 more than 1,100 cases of rubella and 11 cases of congenital rubella syndrome were reported. This is the highest number since 1982 and the highest number of congenital rubella syndrome cases since 1979. This trend continues in 1991, and already this year there are over 1,200 cases reported.

Over the past several years, a rise in the number of cases of mumps and whooping cough has also been reported.

There are new demands on programs and the need for new childhood vaccines. Since 1989, the ability of State programs to continue to adequately provide vaccine to their children has been threatened by a number of factors such as the rising cost of vaccines, excise taxes, and recommendations for additional doses of vaccine like the second dose of measles.

In the fall of 1990, Haemophilus influenza type b, or Hib, vaccine was approved for use in infants. This is an advance in child health which many pediatricians say can be ranked second in importance only to polio vaccine. This vaccine will protect infants against invasive Hib disease, which is the most common cause of meningitis in early childhood. It also causes other life-threatening throat, heart, lung and blood infections.

A formal recommendation for universal immunization of infants against hepatitis B is expected imminently from the advisory bodies of the American Academy of Pediatrics and the CDC. The previous strategy of immunizing only high-risk groups and infants born to infected mothers has failed. The incidence of hepatitis B has increased at a rate of 5 to 6 percent per year. Transmission of hepatitis B from chronically infected mothers to infants during the perinatal period has the greatest long-term consequences. At least 90 percent of the infected infants will remain chronically infected, and 10–15 percent of them will die in young adulthood from hepatitis B related chronic liver disease.

Infants not infected at birth remain at high risk of acquiring chronic infection during the first 5 years of life.

These new advances and recommendations are gladly welcomed by State immunization programs, and I expect most will attempt to implement them as soon as possible. However, these changes increase the demands on States that are already struggling to provide existing immunizations, expand access to care, and deal with the outbreaks of measles, mumps, rubella and whooping cough that are occurring.

I'd like to share with you now some experience we have in Massachusetts on dealing with these issues. After the initiation of the National Childhood Vaccine Program in the 1960's, States pur-

chased vaccine at Federally contracted discount rates, and three types of programs evolved amongst the different States to distribute these vaccines. They chose to distribute vaccine to public clinics only, to public clinics, medicaid clients and selective practices or to all providers, public and private, which is universal distribution.

Massachusetts has always been committed to universal distribution, and we are one of approximately 12 States to distribute vaccine to health care providers in both the public and private sectors. In Massachusetts we have either very limited or nonexistent local health department clinics. However, a unique public-private partnership has been forged in our State that allows us to obtain adequate amounts of vaccine and administer it effectively. A schematic of our universal distribution system is in Attachment 4 of the testimony.

Our ability to universally provide vaccine was recently threatened by the factors I mentioned earlier—rising costs, excise tax, recommendations for additional doses of vaccine, and the approval of new vaccines.

The costs for statewide distribution rose from $3 million in 1987 to more than $12 million in 1991. The previously allotted Federal funds from the prevention block grants and the vaccine program and the State funds were inadequate.

In order to demonstrate support for a universal program in Massachusetts and to secure funding, a public-private coalition was formed. This resulted in our legislature creating the Vaccine Trust Fund with revenues from the "uncompensated care pool." The fund will provide more than 70 percent, or $10.7 million, of our vaccine budget this year. The remainder of our funding will come from Federal sources.

We distribute vaccines free of charge to all health care providers in the State. Those providers who participate in our program can charge a small administration fee which must be waived if the patient cannot afford to pay. Thus, in Massachusetts, most children are vaccinated by their primary care provider. In 1990 we distributed approximately two million doses of vaccine and 70 percent of it was administered in the private sector. The remaining vaccine is administered at public sites such as local boards of health, community health centers, public hospitals, and visiting nurse associations.

We believe that our policy of universal distribution has resulted in extremely high immunization rates, as seen in Attachment 5. And our policy has also resulted in a very low number of vaccine preventable diseases, as seen in Attachment 6.

States without universal immunization programs do not enjoy these high rates and have been the sites of large outbreaks of vaccine preventable diseases. Attachment 7 illustrates that most of the measles cases reported in 1990 occurred in States without universal distribution.

While the rest of the Nation was experiencing an epidemic, Massachusetts saw a two-thirds reduction in measles cases. Only 33 cases in our entire State were reported in 1990, and only 37 cases so far this year. Attachment 5 shows that in 1990, 98 to 99 percent of children in kindergarten and daycare in Massachusetts were immunized against measles, and between 87 to 91 percent of our 2

year-olds and 92 percent of our college students are immunized against measles.

Likewise, Massachusetts has not experienced the national resurgence in rubella and congenital rubella syndrome. Since January of 1990, only two cases of rubella have been reported each year, and no cases of congenital rubella syndrome have occurred.

But what are our future needs? The Vaccine Trust Fund has allowed us to supply the second dose of measles vaccine universally and to immunize infants with Hib vaccine. Since February of this year, we have distributed over 385,000 doses of Hib vaccine, and we have already seen a two-thirds reduction in the number of cases of Hib disease in children under 5.

We also want to start new programs. We want to begin immunizing against hepatitis b, and we would like to start planning programs for not-yet-licensed vaccines for diseases such as chicken pox. But to continue existing immunization programs and start new ones, we need additional Federal funds.

Funding for immunization is money well-spent. For example, consider the eradication of small pox. Just two decades ago, this disease was causing illness, debility and death worldwide. But through aggressive immunization programs like the ones I have just described, and international cooperation, smallpox was eradicated from the world in 1979. If interest and funding were available to continue aggressive immunization efforts, we could achieve eradication of other vaccine preventable diseases.

As the National Vaccine Advisory Committee states: "Immunization benefits not only the child vaccinated, but society as a whole. Vaccine preventable diseases are contagious. Outbreaks amongst any group threaten all susceptible children and adults. Because disease occurring in one part of the country is a threat to all, Federal, State and local governments share the responsibility for their control and elimination."

In conclusion I'd like to thank Senator Kennedy and the committee for the opportunity to speak to you about the problems facing childhood immunization programs and our attempts to solve them in Massachusetts. Our preventive immunization program is successful. Our governor and our State legislature are committed to immunizations. But additional funding through the Federal block grant system and vaccine program is critical for us and other States to continue protecting our Nation's children.

Thank you.

[The prepared statement of Dr. Lett (with attachments) follows:]

Prepared Statement of Dr. Lett

Good morning Mr. Chairman and members of the committee. My name is Dr. Susan M. Lett, and I am the medical director of the immunization program at the Massachusetts Department of Public Health. I would like to commend Senator Kennedy and this committee for your support of the Preventive Health and Preventive Services Block Grant and the National Childhood Vaccine Program, and your interest in immunizations. I appreciate the opportunity to come here today to talk to you about these issues. In my testimony, I will review the significance of vaccine preventable diseases prior to the availability of immunizations, I will tell you of the tragedies that occur when we fail to immunize our children, and I'll tell you of the deaths and disabilities they suffer. I will tell you how funds from the block grant and the National Childhood Vaccine Program led to a decrease in cases and deaths

from vaccine preventable diseases over the past twenty years. But, I will also describe how these diseases have recently returned to certain parts of this country where children are not adequately immunized. I will then describe certain aspects of the Massachusetts Immunization program that may interest your committee.

The past four decades have been years of phenomenal progress in all areas of medicine. Yet in terms of lives saved or productive years spared, nothing rivals preventive pediatrics, specifically immunization. Immunizations have long been the cornerstone of preventive health care. Few other health services, whether curative or preventive have proven to be so cost effective. The benefit-to-cost ratio of some of the major childhood vaccines are outlined in Attachment 1. These ratios are based on acute medical costs only and do not include such indirect costs as loss of income. Yet by comparing the cost of the vaccine to the expense of treating the disease they prevent, you can clearly see the value of immunizations

Historical Background

Most people can remember when, in the pre-vaccine era in the United States, 15 to 20,000 cases of paralytic polio occurred each year. Most people can remember how tetanus or "lock jaw" sometimes occurred in adults after puncture wounds. However most people do not remember that:

1. Babies died of tetanus because of infected umbilical cords;
2. 500,000 to 4 million cases of measles occurred each year, with 1,000 to 3,000 deaths.
3. 300,000 to 500,000 cases of pertussis, also known as whooping cough, occurred each year and that in some years between 10,000 and 30,000 people died.

The health complications caused by vaccine preventable diseases can be extensive. They include inflammations of the lungs, heart, brain and other organs, often resulting in permanent damage. Victims can suffer from seizures, permanent neurologic damage (including paralysis and deafness), blindness, and sterility. Birth defects and mental retardation also occur. The care of children with these disabilities places great demands on our public hospitals, schools and rehabilitation programs. For this group, the number of years of productive life lost is enormous. The emotional impact on their families and themselves is immeasurable.

Vaccines against pertussis, diphtheria, and tetanus became widely available during the 1950's, and polio vaccine was first released in 1955. During the 1960's and early 1970's vaccines against measles, rubella, and mumps were licensed. Also during this time, the National Childhood Vaccine Program was created by the federal government and administered through the Centers for Disease Control. This program provided funds to the states to ensure the adequate immunization of their children. Additional resources for state programs were made available through the Preventive Health and Health Services Block Grants. In 1977, a series of national initiatives to reduce cases of vaccine preventable disease was implemented. The initiatives consisted of aggressive disease surveillance and control measures, and the enactment and enforcement of school immunization laws. By 1980, we saw a 98 percent reduction in vaccinepreventable diseases.

Current Status of Vaccine Preventable Disease

During the 1980's, cases of vaccine preventable diseases began to rise. The vaccine preventable diseases that occurred in 1990 are outlined in Attachment 2.

Attachment 3 shows that in 1990, almost 28,000 people contracted measles. Of those, nearly 90 people died. More than half those deaths occurred among children younger than 5. Although the number of cases in 1990 is only 3 percent of the number of cases reported at the time of peak incidence, this is the largest number of cases in a single year since 1978, and the largest number of deaths since 1971. Failure to vaccinate children at the appropriate age was the major factor contributing to this resurgence of measles. In areas where outbreaks occurred, surveys showed that as few as 50 percent of the children had been vaccinated against measles by the time they were two. There were many complex factors contributing to the low vaccination rate. People faced such barriers as inconvenient clinic hours and locations and lack of walk-in services. People speaking a foreign language sometimes cannot communicate with clinic staff. Also, there were missed opportunities when clinic staff failed to use multiple vaccines and sometimes they ran out of vaccine. Some of these problems were exacerbated when public clinics became overburdened by patients who once could afford private care. The increase in patients switching from private to public health care will continue with the current recession.

A national resurgence in rubella and congenital rubella syndrome (CRS) has also been reported. CRS occurs in children whose mothers acquire rubella during pregnancy. The defects associated with it include mental retardation, severe cardiac and eye problems, deafness, bone deformities and growth retardation. In 1990, more than 1,100 cases of rubella and 11 cases of CRS were reported. This reflects the highest number of rubella cases since 1982 and the highest number of CRS cases since 1979. This increasing trend continues in 1991. Over the past several years a rise in the number of cases of mumps and whooping cough has also been reported.

New Demands on Programs and the Need for New Childhood Vaccine

Since 1989, the ability of state programs to continue to adequately provide vaccine to their children has been threatened by a number of factors, such as the rising costs of vaccine, excise taxes, and recommendations for additional doses of vaccine (eg. the second dose of measles vaccine).

In the fall of 1990, Haemophilus influenzae type b (Hib) vaccine was approved for use in infants. This is an advance in child health, which many pediatricians say can be ranked second in importance only to polio vaccine. This vaccine will protect infants against invasive Hib disease, which is the most common cause of meningitis in early childhood. It also causes other life-threatening throat, heart, lung and blood infections.

A formal recommendation for universal immunization of infants against hepatitis B is expected imminently from the advisory bodies of the American Academy of Pediatrics (AAP), and the CDC. The previous strategy of immunizing only high risk groups, and infants born to infected mothers has failed. The incidence of hepatitis B increased at rate of 5–6 percent per year from 1982–1986. Transmission of hepatitis B from chronically infected mother to infants during the perinatal period has the greatest long term consequences. At least 90 percent of the infected infants will remain chronically infected, and 10–15 percent of them will die from hepatitis B related chronic liver disease as adults. Infants not infected at birth remain at high risk of acquiring a chronic hepatitis B infection during the first five years of life.

These new advances and recommendations are gladly welcomed by state immunization programs and I expect most will attempt to implement them as soon as possible. However, these changes increase the demands on states that already are struggling to provide existing immunizations, expand access to care and deal with the outbreaks of measles, mumps, rubella and whooping cough that are occurring.

The Massachusetts Experience

After the initiation of the National Childhood Vaccine Program in the 1960's states purchased vaccine at federally contracted discount rates. Three types of programs evolved to distribute these vaccines. States chose to distribute vaccine to:

—public clinics only
—public clinics, Medicaid clients, and selective practices
—all providers, public and private (universal distribution)

Massachusetts has always been committed to universal vaccine distribution. We are one of approximately 12 states to distribute vaccine to health care providers in both the public and private sectors. In Massachusetts we have either very limited or nonexistent local health department clinics.

However, a unique public-private partnership has been forged in our state that allows us to obtain adequate amounts of vaccine and administer it effectively. A schematic of our universal distribution system appears in Attachment 4.

Our ability to universally provide vaccine was recently threatened by a number of factors that I mentioned earlier. They include rising costs, excise tax, recommendations for additional doses of vaccine and the approval of new vaccines. The costs for state-wide distribution rose from $3 million in 1987 to more than $12 million in 1991. The previously allotted federal funds from the prevention block grants and vaccine program and the state funds were inadequate. In order to demonstrate support for a universal program in Massachusetts and secure funding, a public-private coalition was formed. This resulted in our legislature creating the Vaccine Trust Fund with revenues from the "uncompensated care pool." The fund will provide more than 70 percent or ($10.7 million) of our vaccine budget this year. The remainder of our funding will come from federal sources.

We distribute vaccines free of charge to all health care providers in the state. Those providers who participate in our program can charge a small administration fee which must be waived if the patient cannot afford to pay. Thus, in Massachusetts most children are vaccinated by their primary care provider. In 1990, we dis-

tributed approximately 2 million doses of vaccine, and seventy percent of our vaccine was administered in the private sector. The remaining vaccine is administered at public sites such as local boards of health, community health centers, public hospitals and visiting nurse associations.

We believe that our policy of universal distribution has resulted in extremely high immunization rates, as seen in Attachment 5. Our policy hag also resulted in very low number of cases of vaccine preventable diseases, as seen in Attachment 6.

States without universal immunization programs do not enjoy these high immunization rates and have been the sites of large outbreaks of vaccine preventable diseases. Attachment 7 illustrates that most of the measles cases reported in 1990 occurred in states without universal distribution.

While the rest of the nation was experiencing an epidemic, Massachusetts saw a two-thirds reduction in measles cases. Only 33 cases were reported in 1990, and only 37 cases so far this year. Attachment 5 shows that in 1990, 98 to 99 percent of children in kindergarten and daycare were immunized against measles. Also, 87–91 percent of two year olds and 92 percent of our college students were immunized against measles.

Likewise, Massachusetts has not experienced the national resurgence in rubella and congenital rubella syndrome. Since January of 1990, only 2 cases of rubella have been reported. No cases of CRS have occurred.

Our Future Needs

The Vaccine Trust Fund has allowed us to supply the second dose of measles vaccine universally and to immunize infants with Hib vaccine. Since February 1991, we have distributed over 385,000 doses of Hib vaccine and we have already seen a two-thirds reduction in cases of invasive Hib disease in children under 5 years of age.

We also want to start new immunization programs. We want to begin immunizing against hepatitis b and we would like to start planning programs for not-yet licensed vaccines for diseases such as chicken pox. But to continue existing immunization programs and start new ones, we need additional federal funds.

Funding for immunization is money well spent. For example, consider the eradication of small pox. Just two decades ago, this disease was causing illness, debility and death world-wide. But through aggressive immunization programs—like the ones I've just described—and international cooperation, small pox was eradicated from the world by 1979. If interest and funding were available to continue aggressive immunization efforts, we could achieve eradication of other vaccine preventable diseases.

In conclusion, I would like to thank Senator Kennedy and the committee for the opportunity to speak to you about the problems facing childhood immunization programs and our attempts to solve those problems in Massachusetts. Our preventive immunization program is successful. Our governor and state legislature are committed to immunizations, but additional funding through the federal block grant system and vaccine program is critical for us to continue protecting our nation's children.

[Attachments referred to above submitted by Dr. Lett, follows:]

SELECTED BENEFIT-COST ANALYSES OF VACCINES

Vaccine	Benefit-Cost Ratio
Measles	10:1
	12:1
Mumps	7:1
Rubella	8:1
Combined MMR	14:1
Pertussis	3:1
	11:1
Polio	10:1

Plotkin and Mortimer. Vaccines. Philadelphia: WB Saunders Co., 1988: 597

Attachment 1

Attachment 2

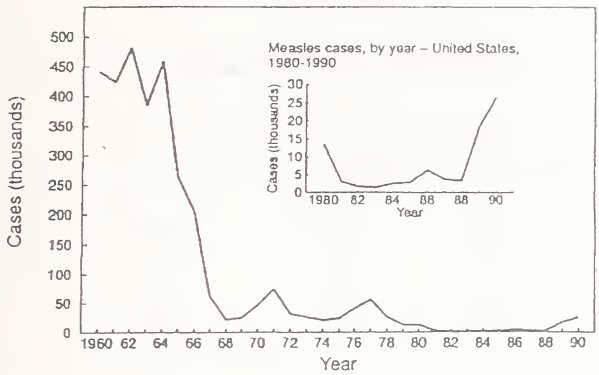
VACCINE PREVENTABLE DISEASES
NATIONWIDE (1990)

DISEASE	NUMBER OF CASES
MEASLES	27,786
MUMPS	5,392
RUBELLA	1,125
PERTUSSIS	4,570
TETANUS	64
DIPHTHERIA	6
POLIO	7

MDPH

Attachment 3

MEASLES CASES PER YEAR UNITED STATES (1960-1990)*



*1990 provisional data

(MMWR 1991;40:369-372)

Attachment 4

VACCINE DISTRIBUTION

MASSACHUSETTS

State Funds — Federal Funds

Immunization Program

Purchase of All Vaccines* on Federal Contract

Central Storage of Vaccine at State Laboratory

Distribution to 6 Regional Depots

Distribution to 193 Boards of Health

Universal Distribution to All Providers

*Exception: Influenza Vaccine

Attachment 5

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
IMMUNIZATION PROGRAM

Immunization Levels in Massachusetts

Table 1
Immunization Survey of Children
Enrolled in Kindergarten and Attending Daycare
(1990-91)

	DTP (1)	OPV (2)	MMR (3)
Kindergarten	99%	99%	98%
Day Care	98%	98%	99%

Table 2
Retrospective Immunization Survey of Two Year Old Children
Enrolled in Kindergarten and Attending Day Care
(1990-91)

	DTP (1)	OPV (2)	MMR (3)
Kindergarten	73%	88%	87%
Day Care	81%	92%	91%

Table 3
Immunization Survey of College Students
(1990-91)

	MMR (3)	Td (4)
Undergraduate	92%	95%
Graduate	86%	88%
Health Science	95%	95%

1 DTP= Diphtheria, Tetanus, Pertussis Vaccine
2 OPV= Oral Polio Vaccine
3 MMR= Measles, Mumps, Rubella Vaccine
4 Td= Tetanus, diphtheria toxoid

(revised 11/91)

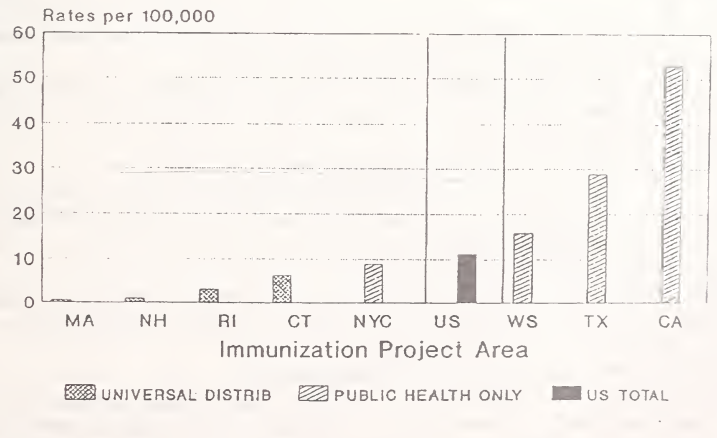
Attachment 6

VACCINE PREVENTABLE DISEASES
Massachusetts (1987-1990)

DISEASE	1987	1988	1989	1990
MEASLES	66	6	109	33
MUMPS	21	4	57	15
RUBELLA	2	15	1	2
PERTUSSIS	153	211	307	366
HIB <5 YRS	147	118	92	99
TETANUS	0	1	0	1
DIPHTHERIA	0	0	0	0
POLIO	0	1	0	0

Attachment 7

1990 Measles Incidence
Selected Immunization Projects Areas



Rates per 100,000 Total population

The CHAIRMAN. Thank you very much. What you have talked about in terms of the universal immunization is very encouraging.

Have you made an estimate of what the cost would be if the decision were made to immunize children for hepatitis?

Dr. LETT. I know what it would cost for Massachusetts to do it. It would cost an additional $2.4 million a year.

The CHAIRMAN. As a person who had the mumps and the whooping cough as a young child, and who has had personal experience with the discomfort of that experience and the anguish, obviously, in a personal way I can certainly attest to the desire of avoiding those diseases.

Let me ask you—in most of our communities in Massachusetts, like southeastern Massachusetts with a cultural and ethnically diverse population, there is a high immunization rate—and I'm sure you know the figures on it—but there are concerns that vaccine preventable diseases may increase because of the cultural differences, and with the immigration bill last year and the illegal immigrants who have come into the United States from countries that don't immunize their children, do you feel that this may contribute to the problem? Also, I have heard from parents down in southeastern Massachusetts that it costs them $40 or so to get immunized, and with 18 percent unemployment down them, many of them are hard-pressed to move ahead on it.

Is this much of a problem?

Dr. LETT. Well, first I'd like to say that linguistic, culturally appropriate access is a problem, and we are working to address that through a series of initiatives to train local outreach workers. But in Massachusetts people should not be being charged $40 a shot for immunizations, and I'd like to know where that is happening so I can address that, and I'd be glad to speak to anyone who is encountering that kind of an economic barrier.

The CHAIRMAN. Don't they have to have the immunizations to gain entry into the school system?

Dr. LETT. Yes, they do. We have very rigorous school immunization laws.

The CHAIRMAN. And if they have not been immunized, what do they do, if you know, down in New Bedford?

Dr. LETT. At New Bedford there are a number of public health clinics available. There are immunization clinics at the local health department——

The CHAIRMAN. So they can get them virtually free.

Dr. LETT. Yes, and at community health centers. They are allowed to charge what is called a "reasonable administration fee," but through a signed agreement with us, they must waive that fee if the patient cannot afford to pay.

The CHAIRMAN. And do you statistics on what percent of children in kindergarten or first grade are covered now in our State?

Dr. LETT. Ninety-eight percent.

The CHAIRMAN. That's very encouraging.

Ms. Brown, your testimony was very compelling, and we appreciate your support on the tobacco legislation. One other area where we need to be doing a good deal more is the battle against substance abuse, as you are probably familiar. It is about 75–25 in terms of the law enforcement versus the demand side, which I

think is skewed in the wrong direction. We need law enforcement, clearly, but we're not dealing as effectively as we could in terms of the demand side. We hear from the drug czar about gateway drugs, which are basically tobacco and beer, in the lower grades of schools. We are interested, and you made a very eloquent statement with regard to the health implications and what happens to young women, and what we might do in terms of our current legislation. But also on the larger scene in terms of gateway drugs, I think a very compelling case is made that it is imperative if we're trying to deal with the other issue that is before the country in terms of substance abuse. If we shortchange the ability to provide that degree of education—and the Michigan studies of young people in high schools are so reflective—this has been documented in the last 5 years—of increasing appreciation of the danger of these items. You see a very significant and substantial reduction in terms of use. This is in addition to school dropouts and hardcore problems that we face in many communities, but there is a very important and dramatic impact.

This is just as true in terms of the issues on gateway drugs of which tobacco is one. So I hope you can help us beat the bushes on the allocation of resources in that area as well.

Ms. BROWN. You have hit on, I think, the primary issue. We have already proven that this kind of an approach works. We have succeeded in convincing 38 million people to give up the tobacco habit, and we have no notion of how many youngsters we have been able to convince to avoid it. This has all taken place not by giving them a pill or anything, but simply by the dissemination of information and the research into and development of behavioral modification programs that do work.

So I am in perfect agreement with you, and I'll beat any bush you'd like me to beat to get more there.

The CHAIRMAN. Well, there's only one around that I had in mind, but I won't ask you to beat that one. Thank you.

Ms. BROWN. Thank you.

The CHAIRMAN. Senator Simon.

Senator SIMON. First, my thanks to all three of you.

Dr. Lett, when I look at our Attachment 7, first of all, universal distribution is clearly something that ought to take place in all States. But when I look at Texas and California, and California with a rate on measles roughly 50 times Massachusetts, is that because the immigrant population there is much higher? Why should those figures be so strikingly different?

Dr. LETT. I believe it is basically because of lower immunization rates in children under 2 years of age. They do have large immigrant populations in California, but the thing about communicable diseases is that although they may start in one community, they move very quickly to all communities, and unless children are vaccinated at a very early age on schedule, they are very susceptible.

Senator SIMON. And in that connection let me just add, diseases don't know boundaries—not only of a community, but of a Nation. One of the things that we ought to be doing is providing much more assistance to other countries.

I am digressing a bit here, but in August I was in Ethiopia. They have about 30,000 former soldiers in camps, many of them wound-

ed I visited one camp that had one physician for 9,000 people. I visited what was called a hospital, with a dirt floor, and I asked, "What are your great needs?" I thought maybe he'd say blood plasma. He said, "Our two big problems are, No. 1, malnutrition, and No. 2, we don't have antibiotics." If you can imagine a hospital without antibiotics. But whether it is Ethiopia or wherever it is, we ought to be reaching out to people and helping with the very fundamental needs.

Ms. Brown, in your testimony you mentioned that in California when a tax of 25 cents per package was levied to support antismoking activities, the use of cigarettes declined 14 percent. Studies—and I believe they were by Harvard—show that when you increase the cost of cigarettes teenage smoking particularly goes down very markedly.

So that when Senator Kennedy and I and others look at where we can find some funds for the Federal Government, one of the places we ought to be looking, on the basis of what you're saying here, is a tax on cigarettes; is that correct?

Ms. Brown. If you made cigarettes $5 per package, you'd probably have the biggest impact you could have on the reduction of young people smoking. So you then run into the problem—it's not a problem, it's really a joy—initially you'll have a lot of money; eventually you'll have none, because hopefully everybody will stop smoking, and your $5 per pack tax will disappear. But the 14 percent came down almost immediately, I think as a combination of the information that was given out for the passage of the initiative as well as for the cost of the cigarettes. And the smuggling of cigarettes that people predicted because of the added tax did not take place.

May I add one other thing, Senator Simon, to your question for Dr. Lett. As Senator Kennedy and Dr. Lett pointed out, by the time—I have been a health commissioner in Los Angeles for a number of years, and you mentioned California and the immunization program—it is true that by the time children reach the age of five, about 98 percent of them are inoculated because of the school demand. However, the problem lies, as I gather it—and Dr. Lett, stop me if I am wrong—by the time the children are ages two and three.

Dr. Lett. That's right.

Ms. Brown. And it's back to the old problem of now money. Now, in Massachusetts they have a wonderful program. In California, it really runs about $120 to get the whole mess of immunizations. That's just too costly for people who, as Dr. Freeman pointed out, are also battling poverty.

So part of your answer lies in those children under five, when they are not yet ready to enter school.

Thank you very much.

Senator Simon. I'm not sure I am ready to advocate $5 a package tax on cigarettes, but——

Ms. Brown. Try it.

Senator Simon [continuing]. I don't think there is any question that if we were to have some kind of an increase we would have an impact on the physical health of the Nation as well as the fiscal health.

Ms. BROWN. Absolutely.

Senator SIMON. You mentioned something that Dr. Pinn also mentioned, and that is the tie-in of poverty with health problems. That is particularly true for women. Sixty-two percent of the people on minimum wage today are women. And in terms of women and health issues and research, Barbara Mikulski, our colleague from Maryland, has been particularly helpful in educating me about the needs that I probably have not been as aware as I should have been.

You mentioned one thing on breast cancer, that it has gone from one out of 20 women to one out of nine. Why that increase, Dr. Pinn?

Dr. PINN. We're not certain why that increase. Some have suggested that maybe we are truly seeing an increase in cancer. Others are suggesting that maybe we have better ways of detecting cancer. I'm not sure we have an actual answer for that except that all data seems to demonstrate that we are seeing more breast cancer. Maybe we're picking it up earlier, but that doesn't seem to always follow through because for women who did live long enough if they'd had a lesion earlier, as we're seeing in young women now, not just older women, I think it would have been manifest. So we're not sure whether it is just due to better methods of detection or whether it is truly on the rise. We tend to think it is probably increasing.

Senator SIMON. I figured by your second day on the job you'd have the answer for us. [Laughter.]

I appreciate what all of you are doing. There is just no question we can do much better as a Nation, and one of the reasons we're going to do better is Senator Kennedy and his leadership. I am grateful to you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Simon.

One effort that I might just draw to Senator Simon's attention is that the World Health Organization tried to make a project for universal immunization, and one of the problems was the issue of refrigeration. Vaccine refrigeration is a problem in developing countries. To complicate this problem, there are virtually no companies trying to explore development of non-refrigerated vaccine because there is no powerful lobby for it except if you were able to get it through these Third World countries, most of which have reasonably decent primary care systems—they have very little else in many instances—but in many instances—not all—they have extraordinary primary care systems, like Sri Lanka and some other countries. The cost to do it 10 or 12 years ago, to purchase the vaccines in other countries, was about $300 million, they estimated. So I know the Senator feels our frustration in recognizing what could be done and what is not being done in that area, and I suggest that sometime—I know you travel—you talk to World Health; there are some rather interesting things going on.

Let me ask Dr. Lett—are we using the killed or live vaccine for polio?

Dr. LETT. We're using the live vaccine.

The CHAIRMAN. Are you satisfied with your own studies versus the Scandinavian countries and others that use the killed vaccine that the live vaccine is still better?

Dr. LETT. Right now there are several advantages to using live vaccine. One is that it is slightly more immunogenic so it protects people a little better. The other is that it actually causes intestinal immunity, so if someone travels abroad and is exposed to polio virus there, they will not come back and infect other people, whereas—this is sort of complicated—if you get the shot, it protects you, but you could still be infectious to others. So that is one advantage to keeping polio out of this country.

I think right now the Centers for Disease Control is looking at a combined schedule where the first two doses would be the killed vaccine followed up by one or two doses of live vaccine. That would eliminate any risk of vaccine associated polio, which you may know accounts for most of the 10 cases that we have every year in the United States.

The CHAIRMAN. That's always one of the great ethical issues. If the mother brings the child down to be inoculated, and that child gets it, even though it says one in a million or one in 1.2 million, and someone else's child doesn't get because he hasn't been vaccinated, yet that child is immunized because of the association with other children in the classroom—there are extraordinary ethical issues, as you well know, and it is an extraordinary dilemma that we looked at sometime ago, but I'm always interested.

I want to thank you all very much. It has been an enormously and moving presentation here this morning. As Senator Simon said, I think all of us are much more aware of the need for focusing greater attention, research, clinical trials and so on on women's issues.

It is amazing to me that women, who are the nurturing factors in our society, have been left out and left behind in so many instances in terms of the research, attention and priorities in terms of health care. I think that has changed importantly, and Senator Simon, myself and the other members of the committee welcome the opportunity to try and be more effective in responding to the challenge.

Thank you all very much. The committee stands in recess.

[Whereupon, at 12:08 p.m., the committee was adjourned.]

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